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HYPERTENSION AND THE ELDERLY: THE NEED FOR FURTHER PROGRESS

H211

HEARING

BEFORE THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

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HYPERTENSION AND THE ELDERLY: THE NEED FOR FURTHER PROGRESS

FRIDAY, MARCH 21, 1986

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
Bridgewater, NJ.

The committee met, pursuant to notice, at 10 a.m., at Bridgewater Senior Citizen's Center, 455 Somerville Road, Bridgewater, NJ, Hon. Matthew J. Rinaldo (acting chairman of the committee) presiding.

Members present: Representatives Rinaldo and Bentley.

Staff present: Mary Polasik and Sarah Richardson, minority research assistants.

OPENING STATEMENT OF CHAIRMAN MATTHEW J. RINALDO

Mr. RINALDO. Good morning. I would like to call this hearing of the House Select Committee on Aging to order and welcome all of our guests here. As the ranking minority member, I think I should tell you that I specifically requested this hearing to examine the significant problem of high blood pressure among the elderly and what can be done to remedy this situation. I am also pleased that my colleague from Maryland is here today, Congresswoman Helen Bentley. I think her presence shows her commitment to fighting this silent killer that often is present without any evident symptoms. Astoundingly, 40 percent of our Nation's elderly are affected by hypertension, which is the major cause of stroke, heart attack, and cardiovascular disease.

Ten years ago, many people believed that hypertension was the same as nervous tension and many hypertensives were taking their blood pressure medication only when they were tense or upset. Since 1972, there has been a public education program sponsored by the Federal Government called the National High Blood Pressure Education Program. They recently reported on the progress of their program—and I would like to share some of the results for the record.

When the National Education Program took its first poll in 1973, less than 25 percent of the people surveyed knew that hypertension was the same as high blood pressure. This doubled by 1982 to more than 50 percent. In 1973, 40 percent of the people polled believed that worry or anxiety was the most important cause of high blood pressure. By 1982, because of the education program, that number dropped to 28 percent.

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While I am encouraged by this progress, I feel that much more still needs to be done to make the public aware of this deadly disorder and to insure that high blood pressure is effectively treated. We need to insure that people know that they have high blood pressure and that they are aware of the fact that they should be checked for high blood pressure.

The focus of treatment for high blood pressure has long been medication. While drugs are indispensable in the treatment of certain hypertensives, research on nutrition should also help us further decrease the incidence of hypertension and possibly provide us with an alternative to drug therapy.

One of the problems in treating hypertension is convincing people to stay on treatment for a problem that does not appear to be bothering them. This problem is further compounded because the drug treatment in some cases causes unpleasant side effects. Because modern drug therapy controls high blood pressure but does not cure it, it must be continued for a long and often indefinite period of time.

Obviously, we do not have the resources in the Federal budget to fund an all-out war on hypertension that would enable us to find the cause, develop a cure, and administer it to all victims of hypertension. I would like to hear from our distinguished witnesses today where our funds would be best spent. Where should the Federal Government use its limited resources? Is it in research, or is it more important in nutrition? Should we spend more money on public education? Are we failing in these areas or should we pursue some different avenue? I would very much appreciate your comments and response to these questions.

It is crucial that we continue the progress that has been made in the past 14 years by the National High Blood Pressure Education Program. The number of elderly people in this country is rising and will continue to increase for many years to come. The magnitude of this problem will increase with time. The cost of the effects of hypertension will continue to plague our health care system.

I want to especially thank all of our witnesses today. I know that Dr. Frohlich, for example, has traveled all the way from New Orleans. Drs. Wood and Jaffe have come from Philadelphia. Dr. Resnick from New York and Drs. Gutkin and Ruddy are resident experts in New Jersey.

We deeply appreciate your presence here today. We look forward to a long and hopefully continuing relationship that will be in the best interest of all the citizens of our country. This hearing is important because of the number of people in this country that have high blood pressure. It is important because of the number of hypertensives who do not know that they have the disease and are walking the streets, in effect, with a ticking time bomb in their pocket.

So I am very grateful, and I know Congresswoman Bentley is, as well as the other members of the House Select Committee on Aging who are not here today. We are grateful for your appearance and the testimony that you are about to offer.

I might also point out to our witnesses that when you testify, you may just summarize your written statement if you like. Your

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entire written statement will then be included in the hearing record, along with any other submissions you may wish to include.

The record is then printed and copies are distributed to all members of the Select Committee on Aging, as well as other Members of Congress. There are over 60 members on our committee. If any of you want copies for your office or for your own personal use, write to the Select Committee on Aging in Washington, and we would be pleased to send you some copies.

I now call on Mrs. Bentley for her opening statement.

STATEMENT OF REPRESENTATIVE HELEN DELICH BENTLEY

Mrs. BENTLEY. Thank you Mr. Chairman. I do appreciate your having invited me to be with you today to investigate the problems that hypertension presents to the elderly. Hypertension, or high blood pressure, as you have pointed out, Mr. Chairman, is the most prevalent, chronic adult illness in America today.

It results in much family tragedy, thousands of lost work days and a great deal of human grief. What alarms me most is that 40 percent of our seniors are diagnosed as having hypertension. This figure alone tells me many elderly may not be aware of the preventive measures that now exist for high blood pressure.

As a matter of fact, several persons very close to me have been diagnosed as having high blood pressure or hypertension. So I have more than a passing interest in this subject. I might also point out, Mr. Chairman, that 23 percent of my constituents are 60 years or older, so they fall right in this category.

The question you have asked of the panel is very important. Where should the Federal Government best spend its funds to help on this illness? I happen to be a nutrition bug so when you mentioned nutrition, my ears perked up. Mr Chairman, without my taking any more time, I would like to welcome our witnesses and commend you on this hearing today. Knowing of your devoted concern for the area of health care, I anticipate an extremely informative hearing.

Mr. RINALDO. Thank you very much, Mrs. Bentley. We will now begin with the testimony and I will call on Dr. Frohlich first.

STATEMENT OF EDWARD D. FROHLICH, M.D., VICE PRESIDENT FOR ACADEMIC AFFAIRS, ALTON OCHSNER MEDICAL FOUNDATION, NEW ORLEANS, LA

Dr. FROHLICH. Thank you very much. Mr. Rinaldo, Mrs. Bentley, members of the committee who will be receiving this report, and staff members. It is clear that when we were advised to present testimony that you people have done your homework in asking for simple language. You have already demonstrated, I think, to those who have been working in the vineyards of the hypertension fields for many years, that you have already learned a great deal about the problem.

My position is that of Alton Ochsner, distinguished scientist and vice president for academic affairs at the Alton Ochsner Medical Foundation and Ochsner Clinic in New Orleans. I am on the faculty of Louisiana State University and Tulane University. I have been a president of the American Society for Clinical Pharmacolo-

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gy and Therapeutics and served on the executive councils of committees of the International Society of Hypertension, and the Council for High Blood Pressure Research of the American Heart Association.

It is a pleasure that I have been serving on the National High Blood Pressure Education Program ever since Secretary Richardson and then Secretary Ted Cooper, who was the Secretary for Health in the HEW in those days, convened the National High Blood Pressure Education Program. At the present time I am serving on its executive committee and as a representative of the American College of Cardiology.

The overall problem of hypertension in the aging patient has received increasing attention in these past 15 years. Appreciation of the problem has increased for several reasons: one, the elderly segment of most Western and industrialized populations has more than doubled during this generation and it is still increasing; two, upwards of 50 percent of the elderly population have either diastolic or what we call isolated systolic hypertension—that is, only the systolic pressure is elevated; three, relatively recent reports have demonstrated that the rise in blood pressure with aging is neither normal nor as innocuous physiological phenomenon; four, decreasing pressure in elderly individuals will be associated with a reduced cardiovascular morbidity and mortality; and five, the recent demonstration of the feasibility of reducing isolated systolic blood pressure by pharmacological means has led to a large National Heart Lung and Blood Institute sponsored multicenter study that is designed to demonstrate the safety and efficacy of drug treatment for elderly people with systolic hypertension.

Much emphasis has been placed over the past three decades on the role of drug treatment of diastolic pressure elevation with ensuing improvement in morbidity and mortality. The emphasis has been appropriate. It was placed because of beneficial findings in several federally sponsored multicenter trials, all of which demonstrated significant reduction in hypertension-related, cardiovascular, and overall morbidity and mortality because of antihypertensive drug therapy.

One very dramatic example of the lesson we have learned from these research efforts has been a 40 percent or more reduction in stroke related deaths in the past 15 years. That has been a major factor.

Therefore, it is not only the elevation of diastolic pressure but also systolic pressure that imparts a tremendous excess risk of death in this country. Systolic pressure elevation is exceedingly common, as you have pointed out, among the elderly.

From critical and fundamental research, new antihypertensive drugs are continually being synthesized. These drugs have accounted for a dramatic reduction in morbidity and mortality during this time. We now appreciate the fact that the rising pressure in elderly individuals has carried with them the same risks as identified for the remaining part of our population. And what is most important to this committee to appreciate is that high blood pressure is ubiquitous in the elderly population, as you have already pointed out, and approaches 50 percent of all elderly individuals.

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The risks of elevated pressure are major catastrophic illnesses: heart attacks, strokes, heart failure, kidney failure, ruptured blood vessels, prolonged hospitalization and obviously, incapacity. The need for continued fundamental and clinical research in the area and enlightened inquiry into the improvement of medical, economic, sociological as well as the political implications of these major concerns should be of urgent priority to our society and its legislators.

With respect to the aging prccess, blood pressure of most individuals in the United States increases with age. There are two ways that blood pressure can rise: by constriction of the arteries so that they offer resistance to the forward flow of blood from the heart and by an increase in the amount of blood pumped by the heart.

In aging, the blood pressure increases on the basis of a progressive increase in the resistance to the flow of blood by the arteries. In fact, the amount of blood pumped by the heart, the cardiac output, decreases with aging. In essence, what I am suggesting is that high blood presssure seems to parallel the cause of the aging process. But perhaps the biological clocks of patients with high blood pressure are running at a faster rate. Research inquiring into the cellular mechanisms responsible for the processes underlying the constriction of blood vessels has and will continue to provide an enlightened approach to diagnosis, management and treatment.

One important recommendation that I might have through this testimony is that we urge continued research through the individual investigator-initiated project mechanism in order to find out these fundamental answers to the underlying problems of hypertension and aging, as well as why they coexist so frequently.

In recent years this research project support has provided new means for the diagnosis and treatment of problems of high blood pressure in the elderly. Among these advances are elucidation of mechanisms involving the kidney in the development of high blood pressure and the understanding of the contractile processes of the muscle in the arterial walls. As a result, a variety of new antihypertensive drugs have recently and continue to come into practice. These major advances have led to the introduction in recent years of beta-blocking drugs, angiotensin converting enzyme inhibitors, the calcium antagonists, all for the treatment of hypertension, angina pectoris, heart attacks and heart failure. Drugs with these actions never existed before and previous drugs were not nearly as effective. Moreover, some of these agents prevent second heart attacks when a first has occurred.

I now want to call your attention to a special conference to be held in Bethesda in May of this year by the American College of Cardiology. This conference is oriented specifically to the problems unique to cardiovascular diseases in the elderly. Each of the areas, including hypertension in the elderly, upon which I am chairing a task force, will be addressed. But I should like to underscore particularly the concern that we have about the multiplicity of disciplines that impact upon the economic, political, sociological and ethical issues of health, health-care delivery, quality of life and the overall economic influence of cardiovascular diseases in elderly patients upon our society. This clearly is not a purely medical issue. It is of vital importance that all of these disciplined areas of social

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concern interact in working out the answers to these highly complex issues of illness, disability and catastrophic disease in our aging population. Those of us who are directly concerned with provision of medical care to our elderly population are keenly aware of rising health-care costs. We are also fully cognizant of the potential of newly developed technological, biological and therapeutic advances that may be provided to our patients whether they be young or old. And because many of these innovations have not previously challenged committed physicians to heightened consciousness concerning the myriad of nonmedical implications, we invite your committee's active considerations.

We therefore strongly urge that the Congress help in providing a tangible impetus to continue with this constructive dialogue in this major area of human concern.

I will now summarize my points of recommendation. Major investigative work and investigator-initiated projects research should be a prime concern for the future of our understanding and treatment of the problem. Second, I think that we have a number of studies that provide further questions as well as answers to these issues of high blood pressure in the elderly. Third, the questions that you pose about nutritional needs require still further investigative answers before they are transferred into major implications that have tremendous economic implications on our society.

Thank you very much.

Mr. RINALDO. We are very privileged to have Dr. Frohlich here today. Thank you, Dr. Frohlich.

[Recommendations submitted by Dr. Frohlich follow:]

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RECOMMENDATIONS OF DR. EDWARD FROHLICH ON FEDERAL FUNDING OF HYPERTENSION RESEARCH

If one were to select specific clinical areas that have benefited from investment in research dollars, the area of hypertensive diseases would have to be at the top of this list:

- Consider the numbers of multicenter studies that have demonstrated the value of antihypertensive treatment.
- Consider the fundamental work that has demonstrated the importance of controlling arterial pressure. And in this respect:
- Consider the fundamental studies demonstrating and elucidating the renin-angiotensin system in: heart failure: malignant hypertension; and the common problem of essential hypertension.
- Consider the elucidation of adrenergic receptors and the development of drugs that inhibit stimulation of these receptors.
- Consider the role of the variety of adrenergic inhibitors that were among the first agents to control pressures for long periods of time.
- Consider the development of beta-adrenergic receptor blocking drugs that not only control blood pressure in patients with mild, moderate, and severe hypertension, but also are used for the treatment of angina pectoris and prevention of a second heart attack.
- Consider the studies that have shown differences in means for controlling pressure between black and white patients with hypertension.
- Consider the studies that demonstrated differences in controlling pressure between lean and obese individuals with hypertension.
- Consider the myriad of studies that have demonstrated demographic and epidemiological trends pointing to a new understanding of disease--its natural history and its treatment.
- Consider the first area of applied scholarship for the discipline of clinical pharmacology and the development of this specialized science for other areas of clinical inquiry.
- Consider the recent exciting finding of the first hormone produced by the heart.
- Consider the elucidation of at least four hormonal systems involving the kidney, each participating in the control of pressure.
- Consider the variety of diseases of the adrenal gland that have been implicated in the hypertensive diseases.

And having comprehended these remarkable advances, let us realize that:

- We still do not know the cause of essential hypertension;

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- Genetic mechanisms are involved in the development and elaboration of hypertension and these have yet to be explored with modern technology;
- It is necessary to understand more fully the role of the hormonal systems involved in regulation of blood pressure and how hypertension and other related diseases result when these mechanisms go awry;
- We have recently described a hormone in the heart but we need clearer understanding of its function and actions;
- We are only now understanding the mechanisms involved in the enlargement of the heart and its regression in size with treatment, and further information is desperately needed;
- We need to understand better those mechanisms that characterize the differences in high blood pressure in black and white, young and old, men and women, lean and obese individuals.

In our comprehension of the fundamentals underlying high blood pressure, not only will we understand more about its causation but also about its treatment, and, most important, about its prevention. And not mentioned is the inextricable relationship between high blood pressure and atherosclerosis (a disease that accounts for coronary heart disease and heart attacks) as well as diseases including diabetes mellitus, gout, and hyperlipidemias (the diseases associated with high cholesterol and blood fats).

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Mr. RINALDO. Our next witness is Dr. Michael Gutkin who is the chief of hypertension at St. Barnabas Medical Center in Livingston, NJ, and the chairman of the Graduate Medical Education Committee.

Dr. Gutkin, you may proceed and you may, if you prefer so there is more time for questions, summarize your statement or give whatever parts you want in full and we will certainly make sure that the entire statement is put into the record as well as any other materials you may have that you want included.

STATEMENT OF MICHAEL GUTKIN, M.D., CHIEF, HYPERTENSION SECTION, ST. BARNABAS MEDICAL CENTER, LIVINGSTON, NJ

Dr. GUTKIN. Thank you, Congressman Rinaldo, Mrs. Bentley, colleagues, guests. First, I wish to thank you and your competent staff for inviting me to testify and for the kind help and guidance that I received in preparing this testimony.

I am a private practioner. I have been privileged to build a practice that focuses almost exclusively on hypertension. I am responsible for teaching hypertension to house officers at our teaching hospital. My concerns will come from that context.

My statement will be abstracted from my written statement but will deviate in content. Hypertension should be viewed as an influence that accelerates the complications of the aging process causing premature damage to the heart, brain, kidneys, and arteries. It is most threatening when it exists in a cardiovascular system which is already jeopardized by other factors such as diabetes, cigarette smoking, high serum cholesterol, and obesity. When left untreated, it can lead to complications such as reduced kidney function and narrowing of certain critical blood vessels which may, in turn, worsen the original problem. Unfortunately, there is more than a chance association between hypertension and high serum cholesterol or triglicerides. So many hypertensives are in double jeopardy from the time their high blood pressure is discovered.

Hypertension has been delineated with artificial boundaries for the sake of convenience. Simple example, a systolic blood pressure of more than 140 milimeters of mercury or a diastolic pressure of greater than 90 have been regarded as high or abnormal. But we must recognize these limits as artificial and regard any given blood pressure harbinger of an equivalent amount of risk. However, even within the range which is considered normal, this risk must not be equated with disease. Some patients with high blood pressure have lived long lives because their body organs resist the ravages of the process. In most instances, the damage to these organs can be measured, not invasively, but safely and repeatedly. Decisions regarding treatment can be made based upon these serial measurements rather than the crude consideration of blood pressure alone.

Thickening of the heart wall and abnormal widening or narrowing of measured blood vessels decreases in blood flow to the kidneys. The presence of coronary artery narrowing and depression of the heart function can be measured conveniently, comfortably, safely, and at relatively low cost. Evaluation of these tests can spare many an elderly patient the expense of unnecessary or harmful antihypertensive drug therapy. While the cost of such repeated

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testing is probably more than empirical drug therapy, it is not an order of different magnitude. Unfortunately, there is no test which can predict the premature advent of hemorrhagic strokes, cerebral hemorrhage, or tiny ministrokes. But due consideration of the level of hypertension, the patient's body habits, and the state of the major arteries can help define those patients most likely to develop cerebral complications.

So, to summarize just a segment of my statement, I think we must consider this as a process and a disease. The distinction between process and disease could rest on observation of damage to so-called target organs; such observation is possible with technology available today.

The effect of hypertension on the brain is most difficult to ascertain. This is unfortunate because the most effective method of preventing complications in the brain is with antihypertensive therapy. But even there, we will be able to narrow in on that problem soon and can to some degree now.

The major advantage of this approach is that it allows the physician to choose which patients may safely defer drug therapy in favor of an interval of nondrug treatment. That interval may vary according to the age of the patient and the presence of other factors which heighten cardiovascular risk. In some hypertensives, successful management of smoking, diabetes, and high blood cholesterol is as important in preventing cardiovascular disease as it is in lowering blood pressure. Nondrug therapy has two major disadvantages, however. First, noone has shown that lowering blood pressure by this means reduces the risk of complications. Secondly, doctors may not be trained in the proper application and monitoring of behavioral therapy. Patients may be unable to adhere to it and do not return for necessary monitoring because of anger, frustration, or guilt over their failure.

Nonetheless, since hypertension is a disease which may get better, worse, or stay the same with passing of time, frequent observation is essential with any form of therapy. It is fortunate that you can get your blood pressure checked at the townhall, your supermarket, or dentist office, at least in New Jersey where there is a program that funds that activity. Especially fortunate is that the information is forwarded to your treating doctor.

We need to train young physicians in an approach to the hypertensive patient which is comprehensive and analytical. Hypertension is like itching. It is bothersome, but is not just to be treated with pills without considering the underlying origin, effects, and results of treatment. A holistic approach is essential and the treating physician should be made aware of the resources available in the community, such as blood pressure monitoring facilities and the services of professional nutritionists and behavioral therapists.

This integrated approach is not featured in medical residency programs which rely heavily on rapid problem solving and an inpatient population. Just as we need to avoid arbitrary definitions of hypertension in deciding whether to treat with drugs, we should examine variables other than blood pressure as end-points of therapy. Large blood vessels can be made less rigid, cardiac performance can be improved and thickening of heart muscle can be reversed.

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These changes can be monitored by the nonbasic techniques already alluded to. Moreover, diagnostic methods can be brought to bear on adverse reactions to drug therapy. Some drug combinations impair cholesterol and sugar metabolism to such a degree that the reduced risk associated with lower blood pressure is algebraically balanced against the increased risk in the resulting higher cholesterol level.

Reduced kidney and cardiac function regularly complicate antihypertensive drug therapy in the elderly. Certain medications may be responsible for increased risk of dangerous abnormal heart rhythms. So there is a need for thorough exposition of these relative risks. How does the risk of untreated hypertension compare with the risk of drug therapy?

Educational programs for physicians are commonly funded through the enlightened generosity of drug companies. While drug companies do not necessarily bias the content of these presentations, they often provide financial backing to reputable, intellectually honest speakers who are chosen because their point of view happens to be favorable to that company's product. Unwary chairmen of departments or chiefs of medicine delighted to present a prominent speaker at no cost to their own budget do not often exercise editorial discretion over program content. Because there are no specialty boards in hypertension, they cannot call on an easily identified expert in their department whose knowledge is sufficently eclectic to construct a comprehensive educational program for staff physicians, house officers, and medical students. In my opinion, hypertension should be organized and taught as a medical speciality.

Mr. RINALDO. Thank you very much, Doctor. We certainly appreciate your testimony. We will now move on to Dr. Resnick who is the assistant professor of medicine at the Cornell Medical College in New York, the assistant attending physician and nutritional specialist at New York Hospital-Cornell Medical Center. Dr. Resnick.

[The prepared statement of Dr. Gutkin follows:]

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PREPARED STATEMENT OF MICHAEL GUTKIN, M.D., CHIEF, HYPERTENSION SECTION; AND CHAIRMAN, GRADUATE MEDICAL EDUCATION COMMITTEE, ST. BARNABAS MEDICAL CENTER, LIVINGSTON, NJ

Hypertension is defined as a systolic blood pressure over 140 mmHg or a diastolic blood pressure over 90 mmHg. Isolated systolic hypertension is a systolic blood pressure over 140 without an elevation of diastolic, and disproportionate systolic hypertension is a systolic blood pressure which is greater than two times the diastolic blood pressure minus 15. Elderly is defined as an age of 60 years or older. Blood pressure is defined as the blood pressure reading obtained on the third consecutive weekly visit to the doctor's office or screening facility, when high blood pressure is identified on the first visit.

The higher the systolic or diastolic blood pressure, the greater the chance of cardiovascular morbidity or mortality. High blood pressure causes premature damage to selective regions of the circulation, the so-called "target organs." As a result, a higher than normal incidence of stroke, transient loss of blood to the brain, dementia, angina pectoris, heart attack, congestive heart failure, kidney failure, hardening of the arteries to the legs, and aneurysms of major blood vessels are increased in hypertensive patients, and the difference between hypertensives and normals is most evident in the elderly. Lowering the blood pressure reduces the frequency of most of these complications.

The differences between hypertensive and normotensive patients might be even more dramatic if we recognize that elderly patients with "normal" blood pressures may be suffering from other incipient illnesses and causes of premature cardiovascular disease inherent in an acculturated western society in which blood pressure tends to rise with age. This rise in blood pressure with age is associated with a rising incidence of cardiovascular complications even when the blood pressure does not exceed an absolute arbitrary "normal" limit. Thus, a rise in blood pressure from 110 systolic to 130 systolic with age could be accompanied by increased cardiovascular morbidity.

Hypertension or rising blood pressure is probably best regarded as a marker for a constellation of risk factors and events which foretell premature cardiovascular disease. For example, in one study of elderly women, two thirds of the strokes observed during the period of observation were noted in hypertensives, but in 96% of cases there were associated risk factors such as obesity, high serum cholesterol, or cigarette smoking. Hypertension is often a marker for the presence of chronic renal disease or of impaired circulation to the kidney. This is commonly unrecognized because the usual biochemical tests of kidney insufficiency are unreliable or insufficiently sensitive in an elderly population.

The World Health Organization regards hypertension as mild, moderate, or severe, according to whether the blood pressure is greater than 95, 105, or 115 diastolic respectively. Since an accentuation of systolic blood pressure and depression of diastolic blood pressure often occurs as the aging process proceeds, this classification is probably

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inadequate for consideration of hypertension in the elderly, but all major trials of the effects of antihypertensive therapy have been based on this diastolic classification. Epidemiologic data suggests that isolated or disproportionate systolic blood pressure with a systolic reading of 180 or greater represents a substantially increased risk of cardiovascular morbidity as well. When hypertension is mild or systolic or isolated systolic hypertension is less than 180, there is evidence that management of associated risk factors such as smoking, diabetes and high blood cholesterol levels is as important at preventing cardiovascular complications as is lowering the blood pressure. These efforts may proceed without antihypertensive therapy since correction of these risk factors, and elimination of alcohol intake, may provide a drop in blood pressure equal to or greater than that induced by antihypertensive therapy. One problem with this approach is that the patient, having received no medication as a reminder of the covenant between him/her and the doctor, may not return for followup and monitoring of behavioral aspects of therapy, especially as the patients' inability to change their behavior leads to a sense of guilt, anger, and futility.

The older the patient who is being observed for hypertension, the more likely the blood pressure will worsen within a short time. When the blood pressure escalates into a range greater than mild hypertension, complications occur with increasing rapidity. Moreover, if blood pressure is not brought down, there is a risk that damage to the target organs will proceed unnoticed. However, as it is increasingly recognized that drug therapy leads to substantial morbidity in the elderly (induction of abnormal cardiac rhythms, decreased kidney function, worsening of high serum cholesterol and diabetes, fainting in the upright posture, severe depression requiring antidepressant medications) the cost of a more saphisticated approach to monitor the effects of the circulation of the nigh blood pressure may be justified. This approach is available with current technology, and in our experience the cost can be reduced as the volume of diagnostic testing increases. For example, PAH clearance-a sensitive measure of decline in kidney blood flow--reveals wide fluctuations in kidney function not detected by routine tests until kidney blood flow is as low as 50% of normal. This test was formerly billed at a cost of $350 at our hospital, but with the aid of a cooperative hospital administration, and our assurance of a predictable flow of patients, the cost of the procedure has now been lowered to $80.

Ambulatory blood pressure monitoring provides an excellent means of sampling blood pressure data from a working day with its attendant stresses, and segregating those patients whose blood pressure rises only on consultation with medical personnel from those with more sustained disease and a higher rate of complications. This procedure has saved many patients from unnecessary antihypertensive therapy, and can be applied repeatedly with a minimum of patient instruction and at a relatively low cost. The effects of hypertension on the heart and the resistance of blood vessels to blood flow, formerly measurable only by expensive and cumbersome means, can now be measured conveniently, relatively inexpensively, and comfortably by methods involving breath analysis or soundwaves reflected from the heart (echocardiography) or aorta (Doppler technique). Thickening of the heart wall-known as left ventricular hypertrophy-makes a patient much more susceptible to heart attack, and much

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more likely to die of a heart attack if one occurs. This complication may be sustained with even mild elevations of blood pressure, especially in black patients, and might call for drug therapy where measurements of blood pressure alone would indicate nonmedicinal therapy. Ultrasound methods are now available to detect narrowing of blood vessels to the brain, which might presage stroke. One important risk factor for stroke-atrial fibrillation-may also be prevented by early recognition and treatment of left ventricular hypertrophy. No convenient, easily administered, or inexpensive testing is yet available to predict which patients might develop the dementia associated with hypertension, but encouraging progress has been made in this area and it may soon be ready for clinical application. Thus, in the setting of conscientious observation of the mildly hypertensive patient, we feel it is quite legitimate and often preferable to treat without drugs.

However, all hypertensive patients should be carefully examined and treated in some manner. The type of treatment is as widely varied as the source of the problem. For example, it is recognized with increasing frequency that many hypertensives suffer from sleep apnea, a condition in which there is repeated interruption of the patency of the upper airway during sleep. Weight loss, an operation to enlarge the airway, or a tube inserted in the nose to keep the airway opened at night might eradicate the hypertension in this instance. While investigation of this problem requires sophisticated understanding, its treatment is substantially different and more specific than just giving the patient diuretics without consideration of the underlying problem. More importantly, an important cause of generalized disability of sapient function will have been eliminated. Simple inquiry into whether the patient is taking drugs or foods which raise blood pressure can lead to a dramatic reversal of hypertension. Environmental factors (loosely lumped together as "stress") can be altered to lower blood pressure without the use of drugs. Cessation of alcohol intake can eliminate hypertension in up to 10% of the hypertensive population. Hypertension is no more a disease than is itching. It is an indication of an underlying problem which a careful, well-trained doctor can detect with elegance and specificity.

Nutritional therapy can be a powerful tool in the treatment of hypertension. This approach to the patient must be marked by the same caveats which apply to all other means of behavioral therapy, namely that the patient must be carefully followed up in the absence of medicinal therapy (which is of proven value). Unfortunately, nutritional therapy, while it is known to lower blood pressure, is not yet of proven value in reducing the incidence of cardiovascular complications from hypertension. This does not mean that it is inferior therapy, only that large scale clinical trials of the effect of nutritional therapy or cardiovascular complications have not yet been completed. Furthermore, nutritional therapy must be monitored closely. For example, sodium restriction is an excellent way of lowering blood pressure in the aged, especially in those with isolated systolic hypertension. However, because the aged kidney might not be able to retain sodium in the face of severe restriction, this can lead to fainting in the upright posture and declining kidney function. Calorie reduction must be carried out in a balanced way in the elderly hypertensive to avoid drastic

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reduction in nutrients and vitamins. Therapy with ions such as calcium and magnesium must be monitored carefully to prevent the harmful effects of their accumulation or excretion.

A holistic approach to mild hypertension or isolated systolic hypertension of less than 180 is essential, and involves a nutritionist, a behavioral therapist, and community and group educational programs. It is best carried out with the physician as the team leader. Unfortunately, there is not universal commitment to this concept by medical educators and virtually no amplication of it in medical residency programs.

Drug therapy of hypertension in the elderly is fraught with risk, and with the wide variety of antihypertensive agents available today, the application would be discrete. For example, while a combination of diuretics and beta blockers, very widely used in the treatment of hypertension, can lower blood pressure by an amount that theoretically lowers the incidence of heart attack, the incidence of heart attack does not change with this type of therapy. This may be related to the fact that depletion of potassium and magnesium by the diruetic, or elevation of blood cholesterol by the combination of the diuretic and beta blocker, represents an adverse effect of equal and opposite weight to the beneficial effect of lowering the blood pressure. Diuretics and beta blockers which do not raise cholesterol are available, but the system of educating physicians to these problems does not function effectively. This is because so much of the doctors' education in antihypertensive therapy relies on educational exercises sponsored by, and sometimes in subtle ways, influenced by drug companies who, in order to maintain profitability, cannot afford an eclectic approach to antihypertensive therapy in the educational programs that they sponsor. To a student of hypertension who reviews many symposia on antihypertensive therapy sponsored by drug companies, an evaluation of the proper approach to the patient can be made after diligent study and appreciation of the bias inherent in these proceedings. Fortunately, our society is sufficiently diverse and affluent to allow numerous such symposia to be published and the information within them evaluated and weighed against that advocated by others. Unfortunately, distillation of this material is not being carried out adequately for the practicing physician who commonly relies on information given by drug company representatives, which while useful, is a poor substitute for well-organized hypertension education programs. There is a need for a hypertension curriculum, sponsored by Departments of Medicine at our medical schools, which teaches the proper approach to the hypertensive patient, teaching all relevant diagnostic and therapeutic techniques in an orchestrated manner, not in piecemeal fashion recognizing any particular technique as the province of "cardiology," "endocrinology," or "nephrology." Once such a curriculum is organized for medical students they will demand a better organized approach from their postgraduate training. They will also be able to evaluate more critically postgraduate educational programs with a given bias.

Whether medicinal or nonmedicinal therapy is applied, the effects of intervention can and should be measured. Reduction in blood pressure is only a hint that the patient's

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circulation may be improving. Physicians must be taught to monitor the patient for improvement or preservation in the function of the circulation using methods which we have detailed above. If these methods were applied on a wide scale basis and without proper education and credentialling of those who interpret them, it could lead to large scale waste and unnecessary costs of funding medical care for the elderly. I cannot say whether application of these methods to monitor the circulation and improve the quality of antihypertensive therapy would be cost effective, and probably no one can. My intuition is that these methods can be widely applied at a reasonable cost and greatly improve the quality of life. Perhaps the increased cost could be more than recovered by increasing productivity of an elderly population unhampered by unwanted effects of medication, enjoying longevity with wisdom, and spending less of the national resources on unneeded drugs.

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STATEMENT OF LAWRENCE M. RESNICK, M.D., ASSISTANT PROFESSOR OF MEDICINE, CARDIOVASCULAR CENTER, THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER, NEW YORK, NY

Dr. RESNICK. Thank you very much Mr. Rinaldo and Mrs. Bentley. I also want to thank you very kindly for having me today to testify. Ladies and gentlemen, blood pressure and nutritional problems have been increasingly recognized among the elderly individuals, who of course represent a growing proportion of our population. There have been some recent advances in medical research which link the dietary intake of minerals such as calcium with high blood pressure, especially in this patient group. This is an exciting new area of research for us, promising both greater understanding of the hypertensive process with aging as well as offering us, I believe, some expanded options in the dietary, nondrug forms of hypertensive therapy.

The hope has been raised, especially in mild hypertension, which is the most prevalent form of hypertensive disease, that dietary, nondrug therapies may lower and maintain normal blood pressure in this age group. At the same time, however, the thirst for knowledge among the society at large makes wide dissemination of medical research advances a feature of our daily life. This popularization and dissemination of current research efforts is sometimes associated with distortion of their meanings, causing health-conscious individuals and groups, often including physicians, to make recommendations on the basis of still evolving, therefore tentative, and perhaps even controversial data.

These trends, therefore, present us with a dual challenge: How can we encourage and continue accumulating relevant new information which might benefit a large percentage of the elderly population without increasing at the same time the potential misuse of only tentative conclusions, which might further aggravate the health of our people? I believe this requires restraint in our recommendations combined with the enthusiastic and vigorous pursuit of new knowledge.

A better perspective of current research advances is needed relating nutrition, specifically dietary minerals, to high blood pressure. Only with this perspective can we hope to formulate an appropriate public response. Furthermore, I believe the essential feature of this response will be fewer global recommendations for all with more specific advice to different targeted subgroups of individuals, each preferentially benefiting from different dietary manuevers to lower blood pressure. Some will benefit from lower salt intake; some will benefit from increased calcium intake, and some from increased magnesium intake. The same advice, for example, either salt or calcium if made to everyone, would benefit some, harm some and be wholly irrelevant to others.

For example, one prominent area of research in the last 5 years in our laboratory has been the role of calcium in high blood pressure. While much information has accumulated implicating calcium abnormalities in the hypertensive process, the exact manner in which these abnormalities contribute to hypertension is not clear. Our group believes that the role of calcium might be better appre-

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ciated and applied in individual subjects by focusing on the underlying heterogeneity among specific subgroups of hypertension.

Thus we have found that a specific chemical pattern helps to define the hypertensive subject most likely to benefit from dietary calcium supplements or from salt restriction. By assessing certain indices of calcium metabolism such as a blood test of the free or ionized calcium level or by measuring the level of hormone renin activity in the blood, we have been able to preferentially select those individuals from among our general hypertensive population for whom salt as well as calcium in the diet tends to be more important. In these individuals, who have a lower calcium and lower renin profile, oral calcium supplements may significantly lower blood pressure as may salt restriction. These responses are found most frequently, by the way, in elderly hypertensives as well as black hypertensive populations.

Furthermore, calcium supplements may help prevent the blood pressure effects of salt in these individuals. Calcium may thus provide an option to those who do not or cannot significantly lower their dietary salt intake.

Now we think this variety of responses among different hypertensives subject to either dietary or drug treatments reflects an underlying heterogeneity of the causes of hypertension and makes it inappropriate to uniformly advise all individuals with hypertension to change their dietary habits in the same fashion. Not only are there some for whom all calcium supplements may be good, and may lower their blood pressure, there are individuals whose blood pressure will be elevated, we believe, by oral calcium supplements. Additionally, there are many for whom no pressure effects would be anticipated at all.

It has similarly been demonstrated repeatedly for decades that dietary salt restriction may benefit some subjects of hypertension, may not benefit others and may actually increase blood pressure in yet others. These being the observed facts, one should refrain from suggesting any public policy incorporating uniform recommendations for the hypertensive population as a whole. The appropriate focus of dietary intervention for hypertension, we believe, should be within the context of the individual physician-patient relationship.

We are at present attempting to generate practical and economic tests that would allow the individual physician to determine if a patient is salt sensitive and would benefit from restricting dietary salt intake and whether he or she is calcium-sensitive, benefiting from increased calcium intake. The information obtained from these tests appropriately remains of intense interest to the public and may very soon become available in routine medical practice.

However, this effort is still presently one of research and no broad recommendations for restricting salt intake or for adding calcium in excess of the U.S. Recommended Dietary Allowances should be made at present. This is entirely consistent with the conclusions recently reached at the 1985 National Institutes of Health Conference on Nutrition and Hypertension in Bethesda, MD, and we believe, reflects a balanced response of the medical research community toward the dissemination and use of the information currently available.

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In summary, global recommendations for the population will inevitably result in benefits for some, but yet harm in others. The necessary inconvenience that individuals encounter when drastically changing dietary habits as well as the attendant economic costs, may be both unnecessary and unwarranted in many cases.

Therefore, in my opinion, the challenge facing social and legislative bodies is to channel the public enthusiasm on this subject into further support for research efforts to appropriately define the role of these dietary mineral nutrients in the hypertensive process. This would encourage the physician, in the best tradition of medical practice, to counsel patients on an individual basis and when appropriate, to attempt to lower blood pressure by nondrug-related strategies. Thank you.

Mr. RINALDO. Thank you, Dr. Resnick.

Our next witness is Dr. Edwin Wood. Dr. Wood is the director of the department of medicine at the Pennsylvania Hospital in Philadelphia, PA, professor of medicine at the University of Pennsylvania, and chairman of the board of the Southeast Pennsylvania High Blood Pressure Control Program.

Dr. Wood, you may proceed.

STATEMENT OF J. EDWIN WOOD III, M.D., DIRECTOR, DEPARTMENT OF MEDICINE, PENNSYLVANIA HOSPITAL, PHILADELPHIA, PA

Dr. WOOD. Thank you, sir. If I could be permitted maybe 30 seconds, I'm bringing some black-eyed susans from Maryland to my son-in-law in New Jersey and I knew that Mrs. Bentley would be interested in them. They are unrelated to hypertension unless they reduce stress in my son-in-law. Now let me give you just a very brief summary of my statement. I think that we now are beginning to repeat ourselves. That's probably good, but it is a little boring. It indicates that this is a basic unanimity of the medical community as to what this disorder is all about, and I am pleased that you seemed to have mastered it so well. We will make this very brief and then tell you about a program in Philadelphia that might be pertinent.

The principal feature of this disorder seems to me to be that a very large number of people have the disorder, hypertension, or high blood pressure. It is critically important and bears repeating that it is very easy to determine whether or not an individual has the problem. A further point that I will take up in a moment in a little more detail is that it is possible to train a nonprofessional person, someone who is not trained in medicine at all, to take blood pressure reasonably accurately in as little as 3 hours.

You pointed out, and it is certainly most important to repeat, that the individual himself cannot discern that he or she has or doesn't have high blood pressure. It is simply not possible. The serious consequences of stroke, heart attack, and renal failure have been mentioned and are worth mentioning. The reason we keep bringing this up is that the disorder is easily treated. Another point that is self-evident but bears mentioning is that it is not only easily treated but very easy to determine success of the treatment. The research over the past 10 or 15 years has clearly and unequivo-

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cably demonstrated that with successful treatment, that is to say, reducing the blood pressure to normal, the incidence of these terrible consequences is greatly reduced. This is not just a guess on our part.

You had mentioned, and we have mentioned, the question of nonpharmacological approaches. I agree with the previous statement that we should not simply develop a public policy that attempts to put these forward because it is simply not possible to know which one will work and which one will not.

On the other hand, public education on these matters is very important because an intelligent, well-informed patient, just as in your own line of work, an intelligent well-informed group of people that you are working for, can do a much better job, and you can do a better job for them. The same is true for us as physicians if our patients know what is going on in terms of blood pressure. Their knowing that weight loss, exercise, possible low salt diet and an approach to stress, is helpful makes it much easier to put it across than if it all comes as new information.

Now, let me say a word about the Southeast Pennsylvania High Blood Pressure Control Program. This is a specific program along the lines that we are speaking of. It is for the five-county area in the Philadelphia area and is supported by money that comes from the State block grant. It is my understanding that the Gramm-Rudman cuts will affect the block grants and this, in turn, will have an effect on the money allocated for high blood pressure. They are relatively small amounts of money. I know you hear this all the time, that everything is just a relatively small amount of money, it is just that it occurs so often when we have a big national budget.

Nevertheless, in the southeast Pennsylvania area, we received a grant of $160,000 and used that last year. This has been going on for many years but I will just give the most recent data. We used that to measure 40,000 blood pressures. We turned up 2,000 new hypertensives. Now, this is sort of cutting through all the data of how many people know, and how many do not, and how many accept it, and how many do not, and so on. In that particular setting, we found 2,000 new, hypertensive individuals. The calculations are that the cost is roughly $75 to find each one of those individuals. It cost us $4 to take each individual's blood pressure. The immediate cost of hospitalization for one individual with a stroke would be $6,000 to $10,000. So a little multiplication and division will tell you that if we got even half of the new hypertensives under treatment, and prevented, let us say, 15 strokes, we would get our money back. If you think in those cold terms.

We have a small staff, but the principal feature of the program is that it is a volunteer effort. The volunteers get very enthusiastic about it and work very hard at it. The bible of this program, which I was surprised Dr. Frohlich did not mention since he worked so hard on it, is the JNC, the Joint National Commission Report on High Blood Pressure which was developed by the National High Blood Pressure Education Program.

The JNC has been the key to enable programs all over the country to have a standard document that we could refer to. It is really true that we use it constantly and all of our volunteers depend on

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it, refer to it, and correct me when I make a mistake that is not in the report. So, you will be pleased to know that.

Critical features are not only taking blood pressures, but followup. It is very important to let the patient know in writing that his or her blood pressure is high. We also let the doctor know. We followup with the doctor and we followup with the patient by telephone. People will not accept it. They say it was just a bad day or whatever and they come back and get it checked again. So we think it is very important that public information indicate to the patient, that he or she get treated, and continue to be treated. Our data indicated this is where the problem is now.

My own background is very much in research. I have not talked about that but I think it is a clear point that we need to constantly look for new information.

Thanks for the opportunity to address you.

Mr. RINALDO. Thank you very much, Doctor. I might comment just briefly on Gramm-Rudman since you mentioned it, because I am sure it is a concern to everyone in the room. Gramm-Rudman fortunately does not have to go into effect. It is merely a club over the heads of Congress. I am hopeful that House Democrats, who are the majority, Senate Republicans, and the administration can come to a consensus budget so that we have an agreement that can pass both Houses and be accepted by the administration. If that is done, I am sure that funding cuts, in a program as important as you mentioned, will be kept to a minimum, or perhaps not even take place. Perhaps even additional funding will be allocated for the program you mentioned.

I feel personally, and I am sure Mrs. Bentley agrees, that cuts with a scalpel, if I put it in medical terms, are better for programs that are needed to preserve the well-being of our elderly and the programs in our country than the meat-ax approach which cuts the good with the bad, right across the board. I am very, very hopeful and I am going to do everything possible to see that that does not happen. So, thank you for bringing that up and I hope that clarifies the Gramm-Rudman situation.

Our next witness is Dr. Michael Ruddy who is the assistant professor of medicine at the University of Medicine and Dentistry of New Jersey. He is also the chief of the section on hypertension. Dr. Ruddy.

[The prepared statement of Dr. Wood follows:]

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PREPARED STATEMENT OF J. EDWIN WOOD, III, M.D., DIRECTOR, DEPARTMENT OF MEDICINE, PENNSYLVANIA HOSPITAL, PHILADELPHIA, PA

Hypertension in the elderly like that of all individuals, is not a serious problem of itself but has very serious secondary effects on the brain in the form of strokes, the heart in terms of heart attack, the kidneys with kidney failure with the need for dialysis, and the blood vessels causing obstruction with the potential need for surgery. The problem is extremely common, involving 20 to 25% of all segments of the population over 35 years of age. The diagnosis of high blood pressure, which potentially can lead to these complications, is easily made with a blood pressure cuff; treatment at the present time is easily applied with minimal side effects. It is well established that treatment reduces the incidence of the various complications both in younger as well as older patients.

Systolic blood pressure (the higher blood pressure of two generally reported) is normally higher in all older individuals, so that this needs to be taken into account in making the diagnosis. Data on the ill effects of excessively high systolic pressure but normal diastolic pressure are well established. Data on the effectiveness of treatment and the potential for reducing the ill effects are not yet completely established. Thus, an abnormal diastolic pressure greater than 95 Hg in an older individual needs to be established on a consistent basis before it can be predicted that various forms of therapy might be effective in preventing complications of hypertension.

The causes of high blood pressure are multiple, but the major category of excess blood pressure in young and old alike has to do with an inherited tendency toward this problem. This inherent tendency in a given individual is influenced by dietary factors as well as psychological stress.

Treatment of high blood pressure is determined by its cause. The major and commonest cause is referred to as essential hypertension. Other causes may be kidney disease, restricted circulation of blood to the kidneys, adrenal tumors, and a few others. These latter forms of hypertension usually demand very specific approaches to treatment, usually surgical in nature.

Treating the commonest form of hypertension by non-pharmacologic means - things that people can do for themselves - involves several avenues of approach. First, salt intake affects blood pressure, thus, the individual can simply reduce the amount of salt in his diet and thus reduce the amount of sodium in his system that tends to cause the blood pressure to go up. Besides monitoring the use of salt in cooking and at the table, the individual can become adept at reading labels and determining which foods have excess salt. The order of

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presentation of ingredients on a label is in the order of concentration, thus, if salt appears high on the list this is a food to be avoided.

Excess weight is not healthy in general, but specifically reducing weight to a normal level will cause elevated blood pressure to come down. This simple measure will have a direct affect on blood pressure. Perhaps related to weight, but in any event a clear cut affect, is that of moderate exercise; even walking twenty minutes a day three times a week will cause a reduction in blood pressure. More vigorous exercise is generally beneficial, but in the elderly person should first be approved by the individual's physician.

Psychological stress, is at best hard to control. Various studies involving attempts at ccontrolling stress have suggested that some reduction of blood pressure can occurr as a result. It seems clear enough that psychological stresses are important to increasing blood pressure. What's unclear is that one can do much about it on an ongoing basis.

If the measures described above are not effective, then elevated blood pressure needs to be brought down by the various drugs available. By now, a number of drugs have been identified as entirely safe for the treatment of high blood pressure in older individuals. This is well established and need not be detailed further here. It is important that the patient work closely with his or her physician in finding the right combinations of medications that will reduce blood pressure toward normal levels.

Finally, it is most important to recognize that hypertension is only one of several factors that contribute to the excessively rapid advance of vascular disease which leads to strokes, heart attacks, kidney failure, and other vascular problems. Controlling high blood pressure is of the greatest importance in preventing strokes. However, reducing blood cholesterol through reduction of saturated fat in the diet will work hand in hand with a reduced blood pressure to further prevent these terrible complications. Finally, it is clearly established that smoking cigarettes and high blood pressure and high cholesterol work additively to cause heart attacks.

In summary then, high blood pressure in all individuals, and specifically in the elderly, is very common and very dangerous, but is easily detected and easy to treat. Detection is inexpensive and can be carried out by non-medical personnel. The needed training can be as little as two or three hours. Once the patient is detected then further programs are necessary to persuade him to see his physician and seek help. Finally, a most important matter is that of persuading individuals to continue treatment.

A major thrust of programs that would be helpful in saving hospital costs for older Americans, as well as saving them the health difficulties involved, would appear to be that of programs which promote detection, which

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promote understanding on the part of patients as well as physicians for the need of treatment, and finally, programs that will persuade both physician and patient to stick with their approach to preventing health problems.

Such programs are inexpensive and have been adequately funded by the block grants, though this is now threatened by the Gram-Rudman cuts. Education is the key to this problem. No program has been as effective as the National High Blood Pressure Education Program. That program has worked very effectively with the American Heart Association and other local programs such as our High Blood Pressure Detection Program in Philadelphia in maximizing the impact at minimal cost.

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STATEMENT OF MICHAEL C. RUDDY, M.D., F.A.C.P., ASSISTANT PROFESSOR OF MEDICINE, AND CHIEF, SECTION OF HYPERTENSION, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, RUTGERS MEDICAL SCHOOL, NEW BRUNSWICK, NJ

Dr. RUDDY. Thank you, Mr. Rinaldo, Mrs. Bentley, and guests. Cardiovascular cerebrovascular diseases remain the leading causes of morbidity and mortality in the elderly, and hypertension is a major predisposing factor for both of these.

With aging, systolic blood pressure rises out of proportion to the increase in diastolic pressure. As a result, a significant number of elderly persons have an elevation of systolic blood pressure without comparable elevation of diastolic blood pressure. This condition, isolated systolic hypertension, has been defined as systolic blood pressure equal to or greater than 150 millimeters of mercury with diastolic blood pressure equal to or lower than 90 millimeters of mercury. Estimates for the actual prevalence of isolated systolic hypertension vary from 10 to 40 percent, depending on the age composition of the population under study. For example, in young adults the prevalence of systolic hypertension is relatively low, in the vicinity of 10 percent. On the other hand, near the age of 80, isolated systolic hypertension may reach a prevalence of about 40 or 50 percent.

Classical views consider diastolic blood pressure as the major determinant of risk in hypertensives. This view probably developed because peak systolic blood pressure only pertains to a small percentage of the cardiac cycle, while the diastolic pressure is the major determinant of the mean or average blood pressure to which blood vessels are exposed throughout the cardiac cycle.

However, there is a growing body of data suggesting that systolic blood pressure is a better predictor of future cardiovascular risks. We know that the size of the elderly population in this country is increasing and that the prevalence of isolated systolic hypertension in that group is high. We also know that the risk of cardiovascular complications is directly proportional to the level of systolic blood pressure. What still has to be learned is whether it is feasible to lower blood pressure with conventional therapy in isolated systolic hypertension in the elderly, and most important, whether such treatment will prevent or delay cardiovascular end points such as stroke, heart attack, and death.

In the past, physicians have been reluctant to treat isolated systolic hypertension in the elderly. Elderly persons may have atherosclerosis of the coronary or cerebral vessels. They may not tolerate the sudden lowering of their habitual blood pressure by antihypertensive medications when used in the doses conventionally utilized in younger individuals. In addition, the increased blood pressure in patients with isolated systolic hypertension is often attributed to a stiff arterial reservoir which may not respond to the usual pharmacological antihypertensive interventions. Therefore, any decline in systolic blood pressure may, in theory, be accompanied by either an unacceptable decrease in cardiac output or a marked reduction in diastolic blood pressure impairing tissue blood perfusion.

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It is becoming important, therefore, to establish the feasibility of treating isolated systolic hypertension of the elderly and the effective treatment in reducing risk.

Now at the Rutgers Medical School in New Brunswick, NJ, we are 1 of 17 medical centers participating in a nationwide study of these important issues. The Systolic Hypertension in the Elderly Program, known as SHEP, will incorporate the results of approximately 4,000 or 5,000 elderly patients followed over a period of 5 years. Each center recruited 200 to 300 elderly patients with isolated systolic hypertension. Each patient is randomized in a double blind fashion into one of two groups. One group receives chlorthalidone, which is a diuretic or if necessary, atenolol, which is a beta blocker, in an attempt to lower blood pressure. The other group receives a placebo medication. All the patients are seen at frequent intervals, at least quarterly, throughout the 5-year course of study.

The SHEP Program is designed to answer the following major questions. No. 1, can isolated systolic hypertension of the elderly be controlled by this form of conventional medical therapy? No. 2, will such therapy produce untoward adverse effects in these patients, such as dizziness, fainting, cognitive defects, or metabolic derangements? And, No. 3, most importantly, will treatment protect against stroke and death? Conclusions regarding these vitally important issues will have a great impact on therapeutic decisions affecting millions of people for the rest of this century and well into the next.

I would also like to address a few comments regarding the issue of atherosclerosis and hypertension. High blood pressure produces vascular disease through a variety of mechanisms, none of which is really that well understood. Most important, however, is the effect of elevated blood pressure on atherogenesis. Atherosclerosis and its major end points, stroke and heart attack, as well as peripheral and renal vascular disease, are the major causes of morbidity and death related to hypertension in the United States.

If current trends continue, 60 percent of the people hearing or reading this report will eventually die of complications relating to one of the eight aforementioned athersclerotic disorders.

Hypertension is the leading correctable risk factor for the ongoing epidemic of cardiovascular disease and death. At the same time, it should be realized that atherosclerosis in itself can induce or worsen the hypertensive process. This effect may occur through several mechanisms. First of all, atherosclerosis may affect blood pressure by stiffening the arterial wall. The resultant decrease in elasticity of the larger arteries causes the systolic component of the blood pressure to rise disproportionately. Such hardening of the arteries is probably the most important mechanism underlying isolated systolic hypertension in the elderly. Atherosclerosis may also produce hypertension by occluding the arteries that provide blood supply to the kidneys. Renal arterial disease may in turn impair the ability of the kidneys to excrete sodium and fluid, thereby increasing blood pressure. Another, perhaps more important, mechanism may be, through the ischemic kidneys, release of an enzyme called renin, which regulates circulating levels of the extremely potent vasoconstrictors known as angiotensin. Just as chest pain, in the form of angina pectoris, is a well known reponse of the heart

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to decreased coronary blood flow, renal release of renin and hypertension are responses of the kidney to decreased renal arterial flow. Atherosclerotic coronary artery disease, the major cause of heart attack, has been and continues to be extensively studied. Many advances have been realized in the diagnosis and treatment of atherosclerotic coronary disease. Much less attention has been paid to atherosclerotic renovascular disease.

We at the Rutgers Medical School, as well as other centers committed to hypertension research and treatment throughout the country, are keenly aware of these important interactions between hypertensive and atherosclerotic processes. We and many others are now employing new clinical, laboratory, and radiologic techniques to determine the safest, least expensive, and most accurate diagnostic methods for atherosclerotic renovascular disease. We and others are also attempting to define methods of individualizing therapy in medical, surgical, or radiologic techniques for patients with various forms of atherosclerotic renovascular disease. Clearly, much more needs to be learned about the causes, prevention, diagnosis, and treatment of atherosclerotic renovascular hypertension, a disorder which although increasing in frequency, is almost entirely confined to the elderly subgroup of our population. Thank you.

Mr. RINALDO. Thank you very much. Our next witness is Dr. Jaffe. Dr. Jaffe is vice president of clinical research for Merck Sharp & Dohme in West Point, PA, and I might also mention that Merck has a facility right in this area not too far from here in Rahway, NJ, as you well know. Dr. Jaffe.

[The prepared statement of Dr. Ruddy follows:]

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PREPARED STATEMENT OF MICHAEL C. RUDDY, M.D., F.A.C.P., ASSISTANT PROFESSOR OF MEDICINE, AND CHIEF, SECTION OF HYPERTENSION, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY, RUTGERS MEDICAL SCHOOL, NEW BRUNSWICK, NJ

HYPERTENSION IN THE ELDERLY

I. ISOLATED SYSTOLIC HYPERTENSION

1. Magnitude of the Problem

With increasing life span, the proportion of older persons is increasing. It is estimated that the number of persons over 65 years of age represents 10% of the population of the United States (22.4 million in 1975). It is expected that it will increase to approximately 50 million by the year 2030. This will result in a tremendous increase in the need for medical services and expense of medical care. Cardiovascular and cerebrovascular diseases remain the leading cause of morbidity and mortality in the elderly and hypertension is a major predisposing factor for both. With aging, systolic blood pressure rises out of proportion to the increase in diastolic pressure. As a result, a significant number of elderly persons have an elevation of systolic blood pressure without concomittant elevation in diastolic blood pressure. This condition, isolated systolic hypertension (ISH), has been defined as a systolic blood pressure equal or higher that 160 mmHg and a diastolic blood pressure equal to or lower than 90 mmHg, although other cut-off points have been used. It is usually accompanied by high systemic vascular resistance and reduced cardiac output, plasma volume, and renin activity.

The prevalence of ISH depends on the cut-off points used for definition of ISH, on the method used to determine blood pressure, on whether a single reading or several readings are performed, and other factors. Estimates for the actual prevalence of isolated systolic hypertension vary from 10 to 40% according to the factors named above and the exact age composition of the population under study. For example, in young persons, the prevalence of systolic hypertension is low, in the vicinity of 10%. On the other hand, at the age of 80, ISH may reach a prevalence of 25 to 40%, both for men and women. In younger age groups isolated systolic hypertension is more common in women and blacks.

2. Risk of Isolated Systolic Hypertension in the Elderly.

Classical views have considered diastolic blood pressure as the major

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determinant of risk in hypertensives. This view probably developed because peak systolic blood pressure only pertains for a small percentage of the cardiac cycle, while the diastolic pressure is the major determinant of mean blood pressure to which blood vessels are exposed throughout the cardiac cycle. However, there is a growing body of data suggesting that systolic blood pressure is as predictive or better predictive of future cardiovascular risk. This was observed in the Hypertension Stroke Cooperative Study Group and in the Build and Blood Pressure Study, which showed mortality increments for each increment of systolic blood pressure for a given diastolic blood pressure. Systolic blood pressure was a stronger predictor of heart disease than diastolic blood pressure in the U.S. Cooperative Group Study. Stroke and congestive heart failure were predicted as well by systolic as diastolic blood pressure. In the Chicago Stroke Study, the incidence of stroke was 2 1/2 times higher in subjects who had isolated systolic hypertension as defined by systolic blood pressure over 180 mmHg with the diastolic blood pressure below 95 mmHg. With criteria similar to those employed by SHEP (systolic blood pressure equal or over 160 mmHg, diastolic blood pressure equal or below 95 mmHg), tripling of the rate of stroke was observed by other investigators. Evidence has also accumulated that hypertension is a significant cause of morbidity and mortality in the older individuals as well as in younger patients. This was observed in the Veterans Administration Cooperative Study where 50% of the morbidity occurred in elderly hypertensive subjects although this group accounted for only one-fifth of the total population under study. The Framingham Study also demonstrated increased risk of stroke in elderly hypertensives. In this study the annualized mortality was increased by about 2 1/2 times in men and women in the 65 to 74 age group. The Pooling Project Research Group compilation of several studies demonstrated a positive correlation between a first coronary event and elevated blood pressure, either systolic or diastolic and this was present in all age groups.

In addition to increased mortality, stroke and myocardial infarction, hypertension is strongly associated with the development of congestive heart failure. In the Framingham Study, hypertension preceded the development of heart failure in 75% of the cases and the risk of developing congestive heart failure was over 6 times higher in hypertensives.

These considerations underline the magnitude of the problem from the epidemiologic point of view. The size of the elderly population in this country is increasing, the prevalence of isolated systolic hypertension in that group is high and ISH increases mortality and the risk of cardiovascular disease (especially stroke, heart attack and heart failure).

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3. Effects of Antihypertensive Treatment on the Risk Imposed by Hypertension

The Veterans Administration Cooperative Trials demonstrated the benefit afforded by antihypertensive therapy on patients with elevated diastolic blood pressure. A beneficial effect of antihypertensive treatment was also seen in the Hypertension Detection and Follow-up Program, including the segment of the population (22%) of that study who were between 60 and 69 years of age. In this group 16.4% reduction of mortality in the stepped care group compared to referred care was observed although the decline in diastolic blood pressure was only about 5 mmHg. The National Heart Foundation of Australia study of mild hypertension in the elderly (diastolic blood pressure between 95 and 105 mmHg) showed 9% reduction in trial end points (death or specified cardiovascular events) among the 293 actively treated subjects. These and several other studies were based on the level of diastolic blood pressure.

In the past, physicians have been reluctant to treat ISH in the elderly. Elderly persons may have atherosclerosis of the coronary, cerebral and peripheral vessels, impaired orthostatic control of brain flow, decreased baroreceptor sensitivity and deficient sympathetic responses. They may not tolerate sudden lowering of their habitual blood pressure by antihypertensive medications and dosages used on younger individuals. In addition, the increased blood pressure in patients with ISH was attributed to a stiff arterial reservoir which is unlikely to respond to the usual pharmacologic antihypertensive interventions. Therefore any decline in systolic blood pressure would in theory be accompanied either by an unacceptable decrease of cardiac output or a marked reduction in diastolic blood pressure, impairing tissue perfusion. These fears were enhanced by the fact that in a randomized clinical trial of antihypertensive therapy in survivors of hypertensive stroke a benefit was not observed in subjects over the age of 65. Also in the Hypertension Stroke Cooperative Study Group of 452 hypertensive stroke survivors no protective effect against recurrence of stroke was found with treatment. It became important therefore to establish the feasibility of treating ISH in the elderly and the effect of treatment in reducing risk.

4. Treatment of Isolated Systolic Hypertension in the Elderly

There are only scant data available on the treatment of ISH in the elderly. The European Working Party on ISH in the elderly has been studying 455 hypertensive patients over the age 60 with ISH to determine the feasibility and advisability of pharmacologic therapy and the potential benefits of treatment.

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These patients receive either placebo or hydrochlorathiazide 25 mg and triamterene 50 with the addition of methyldopa as a Step 2 drug when needed. These investigators have shown that, in the treatment group, the blood pressure was reduced by 25/10 mmHg with statistically significant, but not pronounced, metabolic side effects i.e. decrease in serum potassium and increase in creatinine, uric acid and fasting blood glucose. However, a benefit on cardiovascular morbidity or mortality has not been established as yet.

The second important study is the pilot study of the systolic hypertension in the elderly program (SHEP). In this study 551 participants over the age of 60 with ISH were recruited and randomized to a double-blind placebo control protocol. The study showed excellent compliance and a high rate of response to chlorthalidone alone (75% were at goal blood pressure on chlorthalidone alone over 1/2 of them at the dose of 25 mg a day). The systolic blood pressure dropped by an average of 28 mmHg by 3 months, 30 mmHg by six months while the mean diastolic blood pressures dropped 7 to 8 mmHg. Only 2% of the entire study group reported symptoms considered intolerable and there were no significant differences in reported side effects between the active drug and placebo. Shifts toward lower potassium and higher uric acid but no other differences in laboratory measures were seen with chlorthalidone. The study also demonstrated that behavior evaluation by standardized questionnaires is feasible.

The two studies mentioned above showed that ISH of the elderly is controllable by pharmacologic therapy (especially diuretics) and demonstrated the feasibility of performing a large clinical trial to answer the question of whether pharmacological antihypertensive therapy of ISH in elderly patients reduces the combined incidence of fatal and nonfatal events, especially stroke.

5. SHEP-Systolic Hypertension in the Elderly

UMDNJ-Rutgers Medical School, New Brunswick, New Jersey is one of 17 medical centers participating in a nationwide study to address these important issues. The Systolic Hypertension in the Elderly Program (SHEP) will incorporate the results of approximately 4,000 to 5,000 elderly patients followed over a period of 5 years. Each center, including our own, will recruit into the program 200-300 persons (age 60 and over) with isolated systolic hypertension. Currently, we are well within our recruitment goals. Each patient is randomized in a double-blind fashion into one of two groups. One group receives chlorthalidone (a diuretic) or, if necessary, atenolol (a beta blocker) in an attempt to lower blood pressure. The other group receives a placebo medication. All patients are seen at frequent intervals (every 3 months or sooner if necessary) for the 5 year duration of the study, which will terminate in early 1992.

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Results of the SHEP study is designed to answer the following major questions: 1. Can ISH of the elderly be controlled by this form of conventional medical therapy? 2. Will such therapy produce untoward adverse effects in these patients (such as dizziness, fainting, cognitive defects or metabolic derrangements)? 3. Will treatment protect against stroke and death? Conclusions regarding these vitally important issues will have a great impact on therapeutic decisions affecting millions of people for the rest of this century and well into the next one.

The NHLBI/NIA funded SHEP study should determine whether elderly patients with office/clinic-defined ISH as a whole will benefit from antihypertensive therapy. The SHEP study is not designed to determine whether all such patients will benefit or whether certain subgroups will benefit to a greater extent. This latter issue is of critical importance since elderly patients are more prone to adverse effects of antihypertensive drugs.

6. SHEP-Ancillary Studies

Whether or not antihypertensive treatment of ISH of the elderly proves to be beneficial to the whole group, the SHEP provides us with an invaluable opportunity to learn much more about hypertensive cardiovascular disease and its progression.

Subclinical changes of each of the cardiovascular target organs (heart, retina, kidney) have been previously associated with the presence or later development of more serious, clinically apparent disease in these organs. Furthermore, subclinical changes in any one of these organs have been shown to be associated with cardiovascular damage affecting other organs as well. It is therefore safe to assume that the discovery and follow-up of subclinical hypertensive cardiovascular injury in these organs is a fairly direct and valid means of assessing risk for clinically important cardiovascular disease.

Patients with clinicallly apparent cerebrovascular, cardiac or renal disease at baseline will be excluded for the SHEP study and will therefore not be considered in this present study. It is our intention to investigate the nature and incidence of subclinical/asymptomatic (presymptomatic?) cardiovascular disease in elderly patients with ISH as they enter the SHEP study center. We are utilizing a comprehensive array of highly sensitive techniques to search for evidence of cardiac, retinal, vascular and renal injury in elderly patients with ISH. Our eventual plan is to determine the effects of therapy (vs. placebo) on these sensitive measures of cardiovascular damage. We expect that these findings will provide an enormous contribution to current basic knowledge of hypertensive cardiovascular disease.

Most hypertensive persons are not at significant risk of premature cardiovascular morbidity. Indeed, a great many persons with elevated clinic/office blood pressures live to a very old age, free of complications.

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These individuals may not require blood pressure reduction. A major goal of our proposed ancillary study is to learn more about how to identify those patients who are most likely to benefit from antihypertensive therapy. Much too little is known about this critically important issue. We hypothesize that there may exist a large subgroup of individuals who respond to the stress of a medical office visit through transient elevation of systolic BP, yet have quite normal BP's during 24 hour ambulatory monitoring. These people may be relatively free of even minor subclinical cardiovascular injury and therefore be at lower risk for major cardiovascular damage (eg. stroke, heart disease, renal failure). On the other hand, unusual variability of BP throughout the day may itself produce significant vascular stress as to result in greater likelihood of vascular injury. Our study is designed to resolve these issues.

Another related issue that we plan to address is that of the putative vasculotoxic role of angiotensin. Angiotensin is a hormone that is the most potent blood pressure regulating factor produced in the body. Blood levels of this hormone are tightly regulated by the production of an enzyme called renin which itself is produced by the kidneys in response to a variety of physiological stimuli. It has been hypothesized that components of the renin-angiotensin system may accelerate vascular disease independent from, or in synergy with, their pressor effects. Whereas our sample size will be too small to assess the interaction of plasma renin and major cardiovascular events, we do expect to obtain important information about the relationship of renin to milder forms of cardiovascular injury such as left ventricular hypertrophy, retinal vascular disease and renal dysfunction. Baseline and follow-up renin data that we obtain will be of utmost importance and will help more clearly define the pathogenetic role of renin and its predictive value in human hypertension.

Approval of our present funding request to the National Institutes of Health will enable us to distinguish those individuals at risk for hypertensive cardiovascular damage and who might benefit most from therapy. Such findings may have enormous theoretical and clinical implications potentially affecting millions of present and future elderly persons with ISH. Results of our studies may also serve as a model for future studies in diastolic hypertension.

A year ago we applied to the NHLBI for additional funding for this important series of ancillary studies. Our funding request was approved on its scientific merit but we were unable to secure funding, presumably because of federal budget restraints. We have been able to proceed with a modified version of these ancillary studies on Cardiovascular Injury in Isolated Systolic Hypertension through partial funding by the American Heart

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Association. It is however important to point out that federal sources will be needed for the full completion and interpretation of this vitally important subset of ancillary studies on ISH of the elderly. We have submitted a revised funding application to the NHLBI entitled "Cardiovascular Injury in Isolated Systolic Hypertension" which is currently undergoing scientific review by the Cardiovascular and Renal Study Section.

II. HYPERTENSION AND ATHEROSCLEROSIS

High blood pressure produces vascular disease through a variety of mechanisms, none of which is yet well understood. Most importantly, however, is the effect of elevated blood pressure on atherogenesis. Atherosclerosis and its major endpoints, stroke and heart attack as well as peripheral and renovascular disease are the major causes of morbidity and death related to hypertension in the U.S. If current trends continue, 60% of the people reading this report will eventually die of complications related to one of the aforementioned atherosclerotic disorders. Hypertension is the leading correctable risk factor for the ongoing epidemic of cardiovascular disease and death. At the same time it should be realized that atherosclerosis itself can induce or worsen the hypertensive process. This effect may occur through several mechanisms. First of all, atherosclerosis may affect blood pressure by stiffending the arterial wall. The resultant decrease in elasticity of the layer arteries causes the systolic component of the blood pressure to rise disproportionately. Such "hardening of the arteries" is probably the most important mechanism of isolated systolic hypertension of the elderly. Atherosclerosis may also produce hypertension by occluding the arteries that provide blood supply to the kidneys. Renal arterial disease may in turn impair the ability of the kidneys to excrete sodium and fluid, thereby increasing blood pressure. Another, perhaps more important mechanism, may be through the ischemic kidneys' release of an enzyme, called renin, which regulates circulating levels of the extremely potent vasoconstrictor, angiotensin. Just as chest pain, in the form of angina pectoris, is a response of the heart to decreased coronary blood flow, renal release of renin and hypertension are responses of the kidney to decreased renal arterial flow. Atherosclerotic coronary artery disease (the major cause of heart attack) has been and continues to be extensively studied. Many advances have been realized in the diagnosis and treatment of atherosclerotic coronary disease. Much less attention has been paid to atherosclerotic renovascular disease.

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We at the UMDNJ-Rutgers Medical School, as well as other centers committed to hypertension research and treatment throughout the country, are keenly aware of the important interactions between the hypertensive and atherosclerotic processes.

We are employing clinical, laboratory and radiologic techniques to determine the safest, least expensive and most accurate diagnostic methods for atherosclerotic renovascular disease. We are also attempting to define methods of individualizing therapy (medical, surgical, radiological) for patients with various forms of atherosclerotic renovascular disease. Clearly, much more needs to be learned about causes, prevention, diagnosis and treatment of atherosclerotic renovascular hypertension, a disorder which although increasing in frequency, is almost entirely confined to the elderly subgroup of our population.

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STATEMENT OF MARVIN E. JAFFE, M.D., MERCK SHARP & DOHME RESEARCH LABORATORIES, BLUE BELL, PA

Dr. JAFFE. Mr. Rinaldo, Mrs. Bentley, members of the staff and gracious listeners. I am vice president of clinical research for the Merck Sharp & Dohme Research Laboratories. I am also a clinical associate professor of neurology at the Jefferson Medical College in Philadelphia.

There are four points that I would like to discuss briefly and you can go into these in more detail. The first has been well spoken by all the previous witnesses, and that is the importance of hypertension in the elderly and the tremendous benefits which can be achieved by appropriately treating it. The second is to briefly review, as you might expect from someone coming from the pharmaceutical industry, some drugs which are presently available for the treatment of hypertension, their limitations, and new approaches that may be coming along. The third thing I would like to mention are some new innovations and initiatives which are taking place in the evaluation of drugs in the elderly. These are being sponsored, to a large extent, by interactions between industry, academia and the Food and Drug Administration under the leadership of Dr. Bob Temple. Fourth, I would like to briefly mention some of the public information and educational activities in which industry is involved.

Many people ask why are there so many drugs for hypertension. The reason is that the perfect drug for hypertension has not yet been discovered, and there is a likelihood that it never will be. There are several reasons for this. Hypertension is not a single disease. It has various causes, not all of which are known. Additionally, as previous speakers have indicated, no single drug nor no single approach to therapy meets the needs of all of the patients.

Second, the needs of the individual patient vary for other reasons. The way they handle drugs, so called pharmacokinetics, vary between individuals. Also, the way the drug may affect the individual, pharmacodynamics, differs. Similarly, different classes of drugs have different effects on normal functions of the body separate from the effects on hypertension. Among the drug classes which are presently used frequently, all of them are based on increased understanding of the pathophysiology based on abnormalities associated with hypertension. Included were drugs which eliminate excess salt and water, diuretics, and drugs which reduce the excess activity of the central nervous system and the sympathetic nervous system. Also included are beta blockers, centrally acting antihypertensives and ganglionic blockers.

There are another group of drugs that specifically relax blood vessels, vaso-dilators, and calcium channel blockers. There is also a newer class of drugs which modulate hormone systems coming from the kidneys, called renin-angiotensin systems. Each of these drugs has varied side effects, many of which are limited in their use and are of particular importance to the elderly. Some drugs, such as diuretics, may change the blood sugar complicating the chance of diabetes. Many may increase uric acid causing gout. They may change the blood lipids. Beta blockers, similarly, may have effects in the nervous system causing depression. Beta

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blockers may not be used by asthmatics. They depress the function of the heart. The drugs which affect the renin-angiotensin system, a new class of drugs called ACE inhibitors, seem to have little or no effect on blood sugar, on potassium or lipid or uric acid. ACE inhibitors do not seem to have the cardiac depressants or pulmonary side effects associated with beta blockers. They may present a new approach to the treatment of hypertension, particularly in the elderly, where they are surprisingly effective while apparently not inferior to other quality drugs.

The reason I mentioned the facts that new drugs become available over time and new research is continually producing drugs, is because of the importance of education. There are undoubtedly many persons who would potentially benefit from these drugs who have had unfavorable experiences with previous agents. It is necessary that they be informed when new drugs become available, so they can be evaluated for the suitability of the drugs selected for therapy if it is appropriate for them.

The issue of evaluation of drugs in the elderly was brought to the floor by Bob Temple, Director of the FDA Office of New Drug Evaluation. It is clear to both the pharmaceutical industry and the medical profession in general that the elderly have long been a neglected class in the new drug evaluation process.

I have attached to my prepared remarks a series of book chapters and articles which have originated from my own use. Others are based on a very productive interaction between the FDA, industry, and the academic community sponsored by the American Society of Clinical Pharmacology and Therapeutics, the Drug Information Association and other professional groups.

These interactions are creating an approach to evaluating new drugs in the elderly including an evaluation of: pharmacokinetics; how the elderly handle drugs; and any drugs which may be affected by changes in renal function, by means of changes in bodily composition and changes in sensitivity. These interactions will eventually result in a creation of a new series of guidelines which will be followed by industry and others.

Briefly, let me mention the public information aspects a little more. The variety of speakers of the program today highlighted the interactive nature of medicine, some of the dynamics of how patients are treated, and how drugs and other therapies may eventually come into practice.

The pharmaceutical industry has a role to play in both the professional and public information aspects of medical care as well as in drug discovery, development and the manufacturing process. The industry sponsors, directly, and through academic organizations and professional societies, a variety of educational activities. Many of these are certified for continuing education credits through appropriate peer review organizations.

In addition, audiovisual materials are also made available for the education of both consumers and patients. I have included in my submitted materials and on the table, a variety of materials which I have prepared in cooperation with the American Heart Association and other groups interested in public education. A particularly effective type of film was produced aimed at the elderly featuring the actor, Eddie Albert, and is very popular. The facilities available

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today do not permit a showing but such a showing can be arranged for the committee or for the staff at its convenience. All the materials can be presented to lay audiences and are nonpromotional and contain no product references.

In summary, as far as recommendations are concerned, I would certainly advocate the continuing support of research, particularly the continuing development of public education and awareness in the elderly of particular projects. I also believe, in view of the tremendous educational efforts which the private sector is making, there is not appropriate public funding for educational efforts which might be considerably less biased, one way or another. This is another area that the committee might look at to provide more public information and centralization of such educational efforts. Thank you for the opportunity to speak to you today.

[The prepared statement of Dr. Jaffe follows: 83 pages of supporting material submitted by Dr. Jaffe has been retained in the committee file and may be viewed upon request:]

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PREPARED STATEMENT OF MARVIN E. JAFFE, M.D., MERCK SHARP & DOHME RESEARCH LABORATORIES, BLUE BELL, PA

The perfect drug for the treatment of hypertension has not yet been discovered, and it is likely that it never will be. There are several reasons for this:

(1). Hypertension is a disease with various causes, not all of which are known. Therefore, a single drug cannot meet the needs of all patients;

(2). The needs of individual patients vary. The way they handle drugs (pharmacokinetics) and the way that an individual drug may affect them (pharmacodynamics) differs among individuals and grups of individuals. One of the important patient factors is age and I shall come back to this later.

(3). The drugs vary in their effects on normal functions as well as their effects on hypertension. The balance between the beneficial effects and side-effects of a particular drug is influenced by the disease and patient factors which I mentioned previously and requires that a variety of classes of agents and a selection of agents in each class be available to meet individual patient needs.

The preferred drug classes to treat hypertension has changed over the years. These changes have resulted from an increased understanding of the pathophysiology of hypertension and also due to the ability of science to target on the specific mechanisms that are associated with hypertension.

Four major pharmacological approaches have been taken toward anti-hypertensive therapy and each has a firm theoretical basis. They are:

(1). Elimination of excessive salt and water. The first drugs which were found to be well tolerated in a broad range of patients were the diuretics which were developed as anti-edema (anti-swelling) agents. They were found to be active in lowering blood pressure and became an important first-line therapy. Typical drug names associated with this class of therapies are Diuril® and Hydrodiuril, Lasix, Moduretic and Hygroton. These agents are associated with side-effects which are often tolerated by the patients but which may result in problems over the long term. These include changes in blood sugar which may complicate the management of diabetes, increased uric acid levels and gout, changes in blood lipids and reductions in serum potassium which may result in cardiac abnormalities.

(2). Reduction of excessive activity of the sympathetic nervous system. Agents which reduced sympathetic nervous system activity, the ganglionic-blocking agents were among the first effective antihypertensives. However, their side-effects which included severe dizziness and fainting due to excessive falls in blood pressure made them

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unsuitable for all but the most severely affected patients. Other agents which affected the same systems, but in a more easily controlled manner included Aldomet and Catapres which reduced sympathetic tone by working in the central nervous system and finally the beta-blockers which interfered directly with the action of adrenalin on its target tissues in the heart and on the blood vessels. Popular beta-blockers include Inderal, Corgard, Tenormin and Blocadren. The beta-blockers are well-tolerated by most patients, but they cannot be used in asthmatics nor in patients with depressed cardiac function such as heart failure. In addition, they are frequently associated with depression.

(3). Relaxation of blood vessels. Although many of the agents used for the treatment of hypertension will reduce the tone of the blood vessels and improve regional blood flow, there are some drugs that work directly on the blood vessel to increase its diameter and reduce resistance to flow. These direct vasodilators include Apresoline, Loniten, Minipress and the calcium channel blockers, which are not yet approvd for the treatment of hypertension in the US but are used in this way in Europe and Japan. Due to their direct vascular effects these agents may be associated with headache, flushing, increased heart rate and swelling of the ankles. Therefore, they are usually used as second or third line therapy when other agents such as diuretics or beta blockers do not provide adequate blood pressure control.

(4). Modulation of the renin-angiotensin system. The newest approach to the treatment of hypertension involves an interactive control system which is sensitive to changes in fluid and salt concentrations and the adequacy of blood flow to the kidney. The renin-angitensin system, is a pivotal link in blood pressure control. Recently two agents, Capoten and Vasotec, have become available which inhibit the angiotensin converting enzyme, a critical link in this system. This is an exquisitely specific approach to blood pressure control, and one which is apparently well tolerated by most patients. In our studies of Vasotec we have found that it is not associated with the alterations of blood sugar, potassium, lipids and uric acid which are characteristic of the diuretics and it does not have the cardiac depressant and pulmonary side-effects of the beta blockers. Patients on ACE inhibitors, as these agents are called, also do not have the adverse mental symptoms of the beta blockers and centrally active agents. Thus it appears that the ACE inhibitors are a very promising new approach to the management of hypertension which provide excellent efficacy while not interfering with the overall quality of life.

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Many of the side-effects which I mentioned are particularly worrisome in elderly patients who tend to have associated metabolic, cardiac and pulmonary abnormalities. Therefore we carried out a series of special studies in the elderly. We found that Vasotec was quite effective and well-tolerated in elderly patients and presented no evidence of unusual pharmacokinetics or drug interactions.

Because of the promise of agents of this sort both in regard to efficacy and excellent tolerance, Merck and other companies are exploring new agents that work in this system, both new ACE inhibitors and also renin inhibitors.

Another active area of research involves new approaches to control of fluid and electrolyte abnormalities. This invovles a search for new agents, which may be more effective in controlling salt and water balance than current diuretics, but which will not have the potentially serious metabolic effects of current therapy.

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Mr. RINALDO. Thank you very much, Dr. Jaffe. We now proceed to a question and answer period. Some questions will be directed to specific physicians while others will be directed to the panel as a whole, where anyone who wants to can respond. I might also mention to guests that anyone present who wants a complete copy of the hearing record can write to me at 2338 Rayburn House Office Building in Washington. Alternatively, call either my Green Brook or Union, NJ, offices and we would be pleased to obtain a copy for you. I would like to call on Mrs. Bentley for any questions she may have.

Mrs. BENTLEY. I just have a couple of quick questions, Mr. Chairman. All of our panelists know their subjects so well and presented them so thoroughly that anybody who wants to learn anything about hypertension or high blood pressure need only get the record. After spending a whole day reading it carefully, they will become much more knowledgeable than they were before. Dr. Resnick, you mentioned calcium. In these days we hear a great deal, especially in cases of older women, that they should take calcium tablets and other supplements to prevent osteoporosis. If they do that, can calcium tablets have an adverse effect on hypertension?

Dr. RESNICK. Nature may be fortuitous in that the same sort of tendency toward age-related bone loss seems to run parallel with their need to maintain their bones with calcium. It turns out, of course, as the population ages, blood pressure also goes up. We think it is relevant that the elderly with hypertension, if you chemically attempt to profile what kind of hypertension they have with respect to calcium, are the same kind of people who might benefit, with respect to both their blood pressure and bone disease, by taking extra amounts of calcium.

So, the answer has never been put as you are putting it. That is, there is not one study that has been published where patients with osteoporosis, women with osteoporosis, who were placed on extra amounts of calcium were followed for months or years. On average these people's blood pressure goes down not up. However, we still think that we should take people on an individual basis. When they begin with a medical disease, hypertension, they should go to a physician and be treated as an individual. But in terms of trends, the same people that are taking calcium for their bones may very well, as a general group, benefit with respect to their blood pressure.

Mr. RINALDO. Excuse me, will the chairlady yield for a moment?

Mrs. BENTLEY. I yield.

Mr. RINALDO. Those are very interesting points you bring up about the relationship that exists and the fact that calcium can either decrease or increase blood pressure. You say that treatment should be done on an individual basis. You also state in your testimony, as I have here, that some will benefit from lower salt, some from increased calcium and some from increased magnesium intake. On the other hand, you said that increased calcium could also be harmful to some people. What about the great percentage of the population who take vitamins without any medical advice whatsoever, and perhaps buy a jar of magnesium calcium tablets and take only what is known as the minimal accepted daily requirement supplement? In other words, one calcium tablet a day. I

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do not know off the top of my head how many milligrams that would be.

Mrs. BENTLEY. 600.

Mr. RINALDO. If it is 600, thank you. Would those people then be in danger of increasing or contracting high blood pressure if they do not have it? Perhaps the women are taking the calcium pill solely hoping to prevent osteoporosis?

Dr. RESNICK. Well, a few things. Let us start from where I think we should end up, and that is common sense. What I learned in grammar school which I understand, thank goodness, is still true, is that there are different kinds of foods. People should have a moderate amount of foods in various food groups. The virtue of doing that is to achieve and maintain an adequate nutritional status. It turns out that is still true. Our problem with the elderly population is twofold. With increasing age, peoples' intake of virtually everything decreases. Therefore, peoples' requirements for certain things, like calcium, may increase with age, but at the same time they need more, they may be taking in even less than minimum requirements.

So the primary source of nutrients, I believe, whether we are talking about minerals like calcium or other things that may be important to blood pressure or bones, should be food. That is the way nature packaged it. The percentages of all of the minerals are there. Do not forget the knee bone is connected to the thigh bone. I made mention of calcium, but potassium and salt, which has not been mentioned, are important. Nature has these things in proportions. The first and main source for these things should be food.

Second, not only is there a tendency toward deficiencies of certain things, but people tend to read a lot because they are interested. They know they are getting older and are worried about being frail, getting diseases, and dying. So the elderly are a target for all sorts of things, which almost every store on the block will put into pill form, so that people wind up taking extra amounts.

If you eat an adequate diet in terms of calcium intake, and take a multivitamin that has the standard 400 units per day of vitamin D and if people then want to add on top of that, they have access to calcium pills, some of which have extra vitamin D. So people can take three or four calcium pills which have vitamin D, each pill having extra vitamin D in addition to the vitamin D they may have gotten in the regular multivitamin. Nowadays people hear that fish oils are great so they may take cod liver oil pills and of course, cod liver also has vitamin D as well as vitamin A and a few other things. So these multiple sources each may add up and produce, paradoxically, not the deficiency that everybody was worried to begin with, but really the opposite. An excess in vitamin D intoxication is a growing concern in people who have taken all of these sources of vitamin D.

The reason why I emphasize the individual patient-physician relationship is because in the absence of individual supervision, you have people really doing experiments on themselves. We did not realize this until a few years ago. I am not picking on any one particular substance because I think it in particular is wrong. Nobody ever had experience with people eating the equivalent of 2 or 3 bushels of oranges because nobody would eat 2 or 3 bushels of or-

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anges. But people, by taking huge amounts of vitamin C, never knew that vitamin C could, for instance, raise cholesterol levels. Blood pressure does not rise significantly in most people, but in some cases it goes up.

Mr. RINALDO. Excuse me for interrupting. I think, for the people who are present, would it be possible, when you refer to huge amounts, to state what range is a huge amount? Is a huge amount 1,000 milligrams, 2,000 milligrams or 10,000 milligrams? I do not know.

Dr. RESNICK. Fifty or 100 or maybe 200 milligrams per day. Certainly, when you are taking grams of vitamin C it may very well not be harmful and may even be beneficial in some circumstances. But physicians never even knew what some of the potential side effects were until people, without asking anybody, went ahead and took huge amounts of these things. Zinc is "in" as a mineral now. We did not know that until people started taking a lot of zinc. Researchers then tried to follow peoples' habits to see what the possible consequences were. You can develop a copper deficiency by eating zinc and not getting the right percent of copper in it. That is because nature packages zinc along with other minerals and the right proportions are already in the food. Zinc is good for you in various circumstances. But if you just take it indiscriminately, you may wind up creating a copper deficiency in yourself.

Both copper deficiency and vitamin overdoses can potentiate atherosclerosis. They can increase the aging process. They can produce exactly the same consequences that people are taking various kinds of food additives to prevent. It is these kinds of noncontrolled experiments that people are doing on their own that ought to be pursued in a research fashion. At the same time we can find out what the benefits and risks are for some people. As I said, as the years go on and people are taking more of these things, we are finding out more about them.

I do not know if that exactly answers your question. I think we should begin with diet. After plain old-fashioned balanced diet, if there is an indication, by either family history or prior nutritional deficiency, that extra amounts outside of the diet are needed, we should then select what we think might be necessary.

Mrs. BENTLEY. OK, I just have one more quick question because I have to catch a train. Dr. Ruddy, you referred to hardening of the arteries, and I remembered that as I grew up, all I heard about was hardening of the arteries. Now, we hear about Alzheimer's disease. Some people say that Alzheimer's disease is what hardening of the arteries was. Are they related?

Dr. RUDDY. Well, that is very difficult to answer.

Mrs. BENTLEY. I may not be able to stay for the whole answer but will read it in the record later.

Dr. RUDDY. That will make it easier for you. Basically, nobody knows. Alzheimer's disease can occur in relatively younger individuals who have no clear-cut evidence of atherosclerosis so Alzheimer's is probably some other kind of disorder in the brain itself and probably independant of atherosclerosis.

Mr. RINALDO. I think Dr. Frohlich wanted to make a comment.

Dr. FROHLICH. The point that I wanted to make concerns the nonpharmacological mechanisms and modalities that we have been

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talking about for the treatment of high blood pressure, particularly in the elderly. Dr. Wood was kind enough to refer to the Joint National Committee's report that emanated from the National High Blood Pressure Education Program. This is the program that runs on a low budget out of the Heart, Lung, and Blood Institute and has done so much.

Mr. RINALDO. I am familiar with the program and I agree with you.

Dr. FROHLICH. There is a second group that is coming out very shortly to parallel this, the National Cholesterol Education Program. In the Heart, Lung, and Blood Institute's High Blood Pressure Education Program, we just had two reports that I would like to put in the record. They will be published very shortly. A report on hypertension in the elderly will be published in the AMA Journal in the next few months. Another report on nonpharmacological treatment, which I chaired, will be published in May in the Journal called "Hypertension."

Mr. RINALDO. Excuse me. Doctor, do you have those here?

Dr. FROHLICH. No, they are not yet published. They will be available and as soon as they are I will forward them to you.

Mr. RINALDO. We will keep the file open for the inclusion of both.

Dr. FROHLICH. What I want to point out is that in this report, there are three nonpharmacological modalities which we recommend. One is weight reduction. That has not been talked about and obesity is still a major problem in the elderly.

Mr. RINALDO. May I interrupt you for a moment? I just want to make one point. I have a number of questions here, some of which were submitted by other members of the committee, and you are touching on one right now. So maybe, you can wrap it all up in one answer if you do not mind. Weight reduction is a question that has been posed to members of our committee. This may be a question for all members of the panel. What a number of Members of Congress would like to know is if hypertension can ever be controlled by nonpharmacological treatment. Second, and it was mentioned by one of you, can weight reduction alone cure hypertension without any medication? Maybe that can all be tied in.

Dr. FROHLICH. There are some people with high blood pressure whose body weight is in excess of the ideal. If you can reduce their weight you thereby control pressure. In other individuals who require drugs, we may even have the opportunity to decrease the amount of drugs that they are taking with weight reduction. But we have got to recall that the rate of recidivism with people who are losing weight is exceedingly high. As soon as they regain weight, as they want to as human beings, blood pressure will go back up.

There are two other means of nonpharmacological modalities. One is sodium restriction and the other is alcohol excess. Probably the greatest curable form of hypertension is in those people who consume excess amounts of alcohol. Amounts in excess of 4 ounces a day can jeopardize the amount of blood pressure rise in these individuals.

Mr. RINALDO. What is 4 ounces, about two drinks, would you say?

Dr. FROHLICH. An excess of two shots a day. The Joint National Committee's third report included specifics on each of these points.

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Our review paper, which will be sent to you when it is published, details this.

Alcohol—less than 2 ounces a day, or about one or two drinks, will not raise pressure. But in people who have exceedingly more than this intake, their pressure will rise.

All other modalities of nutritional means have not yet been shown with definite proof to control pressure. The public in general wants to use nonpharmacological modalities. However, most of the studies are of a duration of 1 to 6 months and no longer. We do not have long-term studies with sodium, calcium, magnesium, and others that you, as the Congress, have written into the Food and Drug Administration laws with drugs. The public experiments with each of these food modalities by purchasing nonlicensed drugs that come from within the state in terms of food supplements. Changing their pressure when the efficacy and safety of this has not yet been demonstrated is a major concern that most of us in the hypertension field have. I do not think there is any difference among our feelings concerning this, but that is just the state of our knowledge.

Mr. RINALDO. Obviously, you make a point about something that certainly we have a responsibility to include in publications that go out to the general public. But, yet every day, and I have a whole file here given to me by my staff, there are various publications. For example in Prevention magazine, Dr. Burton Alturo of New York State University Downstate Medical Center in Brooklyn feels that he has uncovered the puzzle. He claims it is magnesium and that you should take magnesium. And in another article, Dr. David McCarron of the University of Oregon Health Science Center found that people with hypertension tend to consume diets low in calcium. He advocates more calcium. Dr. William Peck, Chairman of NIH Consensus Panel, and physician-in-chief of the Jewish Hospital in St. Louis, is quoted as saying, at best, a large group will benefit. Since calcium is safe and cheap, you might as well take it. People will read this and, in some cases, will write to our committee and say, well there is a physician advocating this, and they take it. There is a Dr. Carter in another article who advocated taking oil of evening primrose. You mentioned cod liver oil; there is another doctor advocating cod liver oil. In the group study he did, while they were taking cod liver oil, their systolic blood pressure dropped an average of nearly 10 points. I am a lay person, and to me, 10 points is a pretty significant drop. When the public at large reads a study and the physician is quoted, along with his credentials, they automatically feel that if it is safe and cheap, and this guy says take it, maybe it will do the trick. That seems to be one of the problems.

Dr. FROHLICH. Precisely, and this is why the National Heart, Lung, and Blood Institute convened the High Blood Pressure Education Program through the Joint National Committee. Every major national professional organization has endorsed the consensus statement as a publication for printing and for dissemination. At the present time, these types of statements are found acceptable because they probably do no harm. But the question that we must ask and you must ask, through the sanctions that the Congress gives to the Food and Drug Administration, is are they advantageous and are they safe? And they have to be both. We cannot just

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banter about these things when we have to provide to the people the fundamental information that at least we can show is advantageous in reducing pressure.

More than that, with weight reduction, with some sodium restriction, and with alcohol, there is nothing more that our committee could demonstrate to write and recommend to the public.

Mr. RINALDO. Would you repeat those items again? You mentioned alcohol.

Dr. FROHLICH. Weight reduction, some sodium restriction, and prudence in alcohol intake. There is some promise in the concerns about calcium, magnesium, and potassium. Nowhere in there did we yet find enough information for file feedback techniques, behavioral modalities and so forth. Yet, these are all grabbed upon by the public because they want something that is, perhaps not a drug. These nonpharmacological modalities still must be demonstrated in the same process that we demonstrate any pharmacological drug.

Mr. RINALDO. You have been very enlightening but I just have one quick followup question. You have not mentioned caffeine. Why not?

Dr. FROHLICH. Caffeine probably has no direct effect in raising the pressure. It is a dilator effect. It promotes blood flow to the kidney, but by itself has not been shown to demonstrate either an adverse or a beneficial affect in reducing blood pressure. Nor, for example, has nicotine. Clearly smoking is not good for one's cardiovascular health, or overall health, but we have no definite evidence that long-term effects will raise one's pressure. Smoking will enhance the chances of death and morbid events in a hypertensive patient even more than in a normotensive patient but does not raise the pressure by itself. Smoking is another factor that is certainly not good for one's health but it has no pharmacological effect on pressure.

Mr. RINALDO. I think I saw Dr. Wood's hand first, then Dr. Jaffe's and then Dr. Gutkin's.

Dr. WOOD. The comment that I want to make I would be surprised if anyone disagrees with, but we have not said it today. The higher the blood pressure, the greater the risk of the patient. That is a well-known fact that we just have not touched on. The higher the pressure, the less likely nonpharmacological means will be effective. This is the general clinical experience. There is lots of data, but any good doctor knows if somebody comes in with a very high diastolic pressure of 115, it is very unlikely that reducing weight, reducing salt or telling the person to take it easy and not be quite so stressed in his life is going to really do anything at all. And that is the person who is likely to have a stroke or heart failure or whatever.

Mr. RINALDO. That is an excellent point. What I would like to ask, could you, or anyone, for the record tell me at what point we move from an area, where nonpharmacological treatment is just a waste of time to where definite medication is needed? You mentioned diastolic pressure of 115.

Dr. WOOD. Well these categories have been defined. A diastolic of 85 to 90, correct me Dr. Frohlich, is defined as an at-risk category but is not clearcut hypertension. Let me make a point. The reason

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I cannot get it straight is because it is a continuum; there are no artificial categories. It is just a general experience that the lower pressures are easy to control.

Mr. RINALDO. Maybe I will put it this way. What are the lower pressures?

Dr. WOOD. Diastolic of 85 to 90 is an at-risk category, 90 to 105, clearcut hypertension, 105 to 115, serious, and then above 115, very severe.

Mr. RINALDO. And that is diastolic.

Dr. WOOD. That is diastolic. In the elderly, as we have pointed out from time to time, systolic tends to drift up as all of us get older. The point has not been made that there is very clear cut evidence from the Framingham study that older people who have high systolic pressure are at greater risk even though the diastolic is normal or near normal.

But what we do not know and are not that clear on yet is whether controlling or reducing systolic pressure will reduce their risk. Common sense would suggest it would, but we do not know that. The reason that we are sort of fuzzy on these diet things is that you have to prove that any given maneuver, pharmacological or nonpharmacological, will work and save lives. That is very hard and very serious.

Mr. RINALDO. I understand, and I know that there is research going on in that area. Now you gave us the diastolic, could you do the same thing for the record for the systolic? I think it would be good.

Dr. FROHLICH. In general, with systolic pressure, the upper limit of normal is defined as 140. Between 140 and 160 is borderline systolic. Above 160 is systolic hypertension. If the diastolic is less than 90, it is called isolated systolic hypertension. Again, I refer the staff to the Joint National Committee report, which had this classification in it. It can be gotten from the National Heart, Lung, and Blood Institute.

Mr. RINALDO. We have a copy of it. I know Dr. Resnick also wanted to comment.

Dr. RESNICK. Sometimes the overzealousness of people in trying to correct their hypertension is matched by the overzealousness of the physician. It is hard to try to achieve a perspective, but we may be overdiagnosing high blood pressure at the very same time that we are still trying to get to those people who we know have old fashioned hypertension.

The life insurance companies knew a long time ago that, if blood pressure is 120 over 80 you are an increased risk compared to somebody who is 110 over 70. But that doesn't mean that everybody ought to be dragged from 120 over 80 to 110 over 70. The fact that it is a continuous spectrum, as just mentioned by Dr. Wood, is one way of saying that you can pick your cutoff point almost anywhere you want and claim that the people just above that cutoff point are an increased risk. It is continuous. It is not clear because the same sort of trials have never shown consistent results, and are still a matter of controversy. This is the case not only in the 85 to 90 category, but even in the 90 to 95 category, the lower of what used to be called mild hypertension. Mild hypertension used to be if the diastolic was between 90 and 105.

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Mr. RINALDO. What is it now?

Dr. RESNICK. Well, now we keep on subdividing things. We are looking for more and more people to be able to tell what is right and good. Then we can lower their blood pressure and maybe they would be better off for it. But, even in the 90 to 95 group, it is not clear that doing anything to these people is going to be helpful. Even if you were to treat 100 people, and get their blood pressure down to below 90, which used to be a targeted figure, maybe 3 or 4 or 5 or 6 or 7 out of the 100 are benefited and the other 93 are not.

I am not saying this is an atmosphere where nobody is having their blood pressure treated and therefore we ought to be beating the bushes and getting all these people to a doctor. But there is an innate inertia to the whole process of enthusiastic education, enthusiastic treatment and the old phrase, therapeutic nihilism, which was begun with Sir William Osler, who said, "whatever else you do, do not do the patient any harm." He put it in Latin and they made him a sir, for saying things like that.

But if you start with that notion as a corner-stone of a doctor treating a patient, one is less impressed by overall statistics if one has to make the decision whether to chance that a single person coming into your office with their blood pressure of 140 over 88 is going to benefit by getting his blood pressure down to 120 over 80. Similarly, the doctor must decide whether to commit a given individual patient to either nondrug treatments or perhaps even drug treatments for the rest of his life, perhaps, in order to achieve a targeted number. The issue has been raised in editorials of medical journals whether it is even ethical to treat everybody, when you know the chance of any given person benefiting is vanishingly small, on the much greater chance that he may get a side effect from something that you are doing to him.

Now, I am saying this only after one already accepts the necessity for detecting hypertension, by using a commonsense approach based on as little as you can do. But if it takes more, do more to get a person's blood pressure down to ranges that everybody has in the past agreed is a reasonable range where patients would benefit.

Mr. RINALDO. All right. I am glad Dr. Ruddy is back because I noticed in your testimony that you stated many persons with elevated blood pressures in the office may have normal blood pressures outside of the office visit and therefore, live to a ripe old age without the need for any medical intervention. Now I guess that is what physicians refer to as the white coat syndrome or at least that is how it is publicized. Now how do you determine if a person in your office is in that particular category of individuals? From what has been said so far this morning, if an elderly person is prescribed medication unnecessarily on the basis of that visit, it could eventually do them more harm than good.

Dr. RUDDY. OK. Let me address several issues related to that question. Yes, it does appear to be true that many individuals have lower blood pressure outside the doctor's office than they have when the blood pressure is measured by the nurse or doctor at the office. What is also true that we have to keep in mind however, is that all the large scale studies that have been published showing the risk of high blood pressure and cardiovascular disease, are based on traditional office or clinic blood pressure recordings. So

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we know that in general as a whole, if you take a large group of people and show that their blood pressure is elevated, then they are an increased risk for cardiovascular complications.

But it is also true that this is not true for every individual who has high blood pressure. Many individuals with elevated pressure do not die of premature cardiovascular disorders. What we still need to find out is which of these individuals are truly at greater risk for stroke, heart attack, and premature death, and which are not. If we could find the individuals who are most at risk, we could accordingly tailor either a nonpharmacological or drug therapy.

Now the question is how do you identify people who have so called, "office hypertension"? There are a variety of techniques, one of which has been around for a while. Simply have the patient measure his own blood pressure at home. In fact, most of my patients are trained to do just that. With relatively inexpensive equipment in the range of $20 to $30, people can purchase their own blood pressure machine, learn how to use it and keep a blood pressure diary. That is quite helpful.

In addition, there are some newer technologies that allow for the automatic recording of blood pressure using an ambulatory 24 hour blood pressure recorder. This can be preset to record blood pressure at fairly frequent intervals, say 10 or 15 minutes for example, throughout the whole day. It can even record blood pressure while the patients are asleep.

What still needs to be determined is what these numbers mean when we see individuals with lower blood pressure in the 24-hour recording or by their own self-determinations at home. What we still need to find out is are these people truly at a lower risk? More studies need to be done in this area. If it does turn out from such studies that ambulatory blood pressure recordings or home self-determinations of blood pressure are better predictors of cardiovascular risk, then this may be something that should have more widespread application in the future.

Mr. RINALDO. Thank you very much. Dr. Frohlich, I think everyone seems to universally agree that the area of hypertension has greatly benefited from what I consider a relatively small investment of Federal dollars when you consider the expense that this disease causes millions of Americans annually. Now given the limited availability of Federal funding which we all understand is taking place, where should the Federal dollars be allocated in the area of hypertension? Where would they do most good? Where would we, in effect, get the most bang out of a buck?

Dr. FROHLICH. Well I think that 40 years of major work with the Federal Government funded research in hypertension through the National Heart, Lung, and Blood Institute has taught us one very important lesson. Fundamental research generated from or initiated by the investigator has been the most effective way of the Government developing new information about the disease. From that information has developed very practical, impactive activities. Whether it be in pharmaceutical industry, or in devices, you know that this can be done. I think there is not an individual in academia that would challenge the statement that the development of investigator-initiated project research has turned over more fundamental and practical information than any other mode of research.

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We have to develop the areas that we do not know. In doing this we are going to train more people that will provide this information for us in the future. Unfortunately, because of restrictions that you are more aware of than I, these budgetary funds are being direly restricted these days. It is going to have an impact, not only on us today, but in the future.

Mr. RINALDO. Thank you very much. Dr. Gutkin, we have discussed weight, caffeine, and alcohol. Why does alcohol increase blood pressure in some instances? Is any research being conducted? Does anyone know of any research being conducted on alcohol?

Dr. GUTKIN. I do not know who is conducting research on the effect of alcohol on blood pressure but there has been some work done to show that alcohol, particularly alcohol withdrawal, raises the activity of the sympathetic nervous system. Alcohol raises certain substances in the blood and at the ends of the tiny nerves that go to the heart and resistance blood vessels. Evidence of excessive activation of the sympathetic nervous system is sweating, trembling, and rapid heart beat. I do not know a further mechanism for this. I believe plasmalemma activity is also elevated, but this can also be viewed as a consequence of sympathetic activation.

One reason people who drink have high blood pressure is that they smoke. This is a problem in chronic lung disease as well. I am using this, if I may, as a turning point to make a little pitch that I think is very important. I think all the speakers would agree that we have all been intently agreeing on the levels of gradation of hypertension, and that there is no question that moderate is worse than mild and severe is worse than moderate.

I think it is important to recognize that while these categories pretty precisely identify populations who are going to be in trouble, they may not be adequate to focus on the patient who needs more or less intensive drug therapy or nonmedicinal therapy. If you have a systolic blood pressure of less than 180, and you are over 60 years old, there is probably as much benefit to you if your doctor successfully reduces other risk factors than if your doctor successfully reduces your pressure. For example, lowering your cholesterol, or reducing a smoking habit.

It seems ironic to me that the classification of hypertension into mild, moderate, and severe came from the B.A. Cooperative Studies conducted primarily by Dr. Freas in the 1960's. These studies were the first to show that effective antihypertensive therapy prevented complications and that the effects were more obvious in the severe group than in the moderate, and more obvious in the moderate group than the mild. I think it is ironic that these studies were conducted on male veterans who were hospitalized for 3 days so that their blood pressure reading was really a prodigious one.

Both the treated and untreated groups had an exceptionally high incidence of cardiovascular disease. That is probably related to the fact that they were heavy smokers. As you know, the cheapest place to get cigarettes is in the canteen at the VA. I think it is ironic that we are all concerned about a reduction in a positive effort. We are all fearful that research will be stilted by reductions in funding, and that public education will be diminished by reductions in funding. Yet I believe there is still an agricultural subsidy to tobacco.

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Mr. RINALDO. Unfortunately, there was tobacco money in last night's reconciliation bill. I recognize the problem and would like you to know I agree with you completely.

Dr. GUTKIN. I am not suggesting that the money be taken from one pocket and put into another. I do not know how often the tobacco subsidy will come for consideration. I am not suggesting that you take the tobacco money and give it to medical research. I do not think that is a bad idea, but I would hesitate to suggest it. I am suggesting, however, that the tobacco subsidy, both the direct subsidy and the subsidy that encourages our veterans to smoke by making cigarettes inexpensive in a veteran's canteen, be reconsidered as a measure which might lead to as much reduction in vascular disease as all theoretical considerations of nonmedicinal therapy.

Mr. RINALDO. It may alleviate some of your concerns to know that in last night's reconciliation bill which passed, and which the President said he would accept and sign, the high cigarette tax was extended.

Dr. FROHLICH. Good.

Mr. RINALDO. You have all been very, very patient and very helpful and I am going to try to end this. I will ask a couple more questions and end in 10 minutes at 12 noon. We are, and I am sure I speak for every member of the committee, very appreciative of the testimony you have given us.

What other things do you think Congress or our committee should do in regard to hypertension because it is such a serious problem? We have looked at a number of diseases related particularly to the elderly. Do you feel we should have a hearing in Washington, for example, in front of the full committee? Do you think there are other things that have to be impressed upon Members of Congress so that specific legislative direction can be taken? Do any of you have any ideas in that regard that you would like to share with me and get on the record?

Dr. RESNICK. I think it would be worthwhile for the Congress to focus on all the things the elderly are being told, not by us to the extent that we represent the medical establishment, but by all public varied sources, whether it is magazines or advertisements, or various other things. I think that would be both informational from a congressional point of view and educational from a public point of view to actually look to see what elderly people are being advised to do and how diverse and how varied all these recommendations are.

Mr. RINALDO. Dr. Frohlich.

Dr. FROHLICH. I have one recommendation, a minor one but I think it is something that has not been addressed. It is in the report that was published in the Archives of Internal Medicine by a High Blood Pressure Education Program on blood pressure devices and how to measure pressures. It was published a few months ago.

In there is a recommendation. We have a large number of blood pressure recording devices that are available for the public. The elderly population uses them a great deal. There is no requirement that these instruments be checked, calibrated, or validated. When I asked the High Blood Pressure Education Committee of these com-

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pany representatives how often they check it, they say monthly. What they mean is they take their 25 and 50 cent pieces out monthly. They do not calibrate it. If there was a requirement, it could be taxed. The money could be used for high blood pressure programs. Each instrument must be certified like we have elevators certified, so that that they operate correctly. The moneys could be used for the High Blood Pressure Education Program that is funded by the Government and would be doing dual service.

Mr. RINALDO. How often should they be validated and checked?

Dr. FROHLICH. I would say, in a public place, at least monthly.

Mr. RINALDO. How about machines that people purchase for home use?

Dr. FROHLICH. I am talking only about machines in the public place, what is in the supermarket, airports, and train stations. Physicians who prescribe blood pressure recording devices for their patients usually have the patients bring them into the their offices where they validate and check them appropriately. But these large machines that are available are not checked. The public is not assured that that reading is correct. We often see an individual roll up his sleeve, put his arm into that machine, and get an invalid report while he is holding his valise in an airport. Just the holding of a valise will raise your pressure 20 millimeters of systolic mercury. I think this is an exceedingly important area that could be done simply and really is not going to infringe on anyone. These companies who use this machine just must police it.

Mr. RINALDO. The company should be doing the calibrating?

Dr. FROHLICH. Well, some validating body in the State could do this. A tax could be paid to a State or to the Federal Government or the airport, or whoever is doing this. The details could be worked out by the legislative body.

Mr. RINALDO. Where followup is indicated, would you all be willing to answer any questions a committee may have in regard to implementing some of your suggestions?

Dr. FROHLICH. Yes.

Mr. RINALDO. Dr. Gutkin.

Dr. GUTKIN. I think Dr. Frohlich made one of the most cognizant points of the morning. I would like to extend his concern to the area of private home blood pressure recording devices. A colleague of Dr. Resnick's, Dr. Pickering, has done a study on these devices and found a wide range of readings far removed from the true readings determined by standard instruments. The experience that I have in my practice in New Jersey is that patients do not bring their machines in for calibration even when they are repeatedly asked. And yet, they persist in making decisions about their own blood pressure medication and frequency of followup based on the readings they get at home.

I do not know how to insist that these machines also be calibrated. Perhaps this is something that might best be done on the State or local level. I think that the potential harm to patients from inaccurate readings from home blood pressure recording devices is perhaps an even more monumental problem than the airport or the drug store machine. I think this is an exceedingly important area to investigate.

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Mr. RINALDO. There is a proliferation of them on sale, I noticed that.

Dr. FROHLICH. They are sold over State lines. I think that, clearly if we can require policing of the pharmaceutical industry of drugs that are then sold locally, there ought to be some way that these home devices are policed on a national basis.

Mr. RINALDO. I know you both seem very concerned over it. I do not know the answer off the top of my head, but I can assure you that as a result of your concerns, we will take appropriate followup action in an effort to determine what can be done. We will let you all know exactly what we come up with. I think Dr. Wood wanted to speak.

Dr. WOOD. Let me attempt an answer to the question you asked regarding a hearing in Washington. It is a little bit of a cumbersome process on the one hand for you, I am sure, as well as for us. But on the other hand, there is something about the process that tends to bring the truth out. We demonstrated this morning that some aspects of hypertension are absolutely accepted by everyone and others are controversial. Then you mentioned the various articles available to the public.

Mr. RINALDO. But I think I mentioned it in good faith because I think a lot of senior citizens read those articles. You know you can buy any of the vitamins that I mentioned over the counter, with no problem at all, and the public buys them. Now hopefully they are restricting their intake to the minimum daily allowance, but if they go beyond that, I can understand how they could get into trouble.

Dr. Resnick, let me ask you this question that I think would sum things up. It seems to be very critical and very important, maybe not only to senior citizens, but to a lot of people. Are there any vitamins or minerals, in your opinion, that may be helpful in lowering high blood pressure, or curing hypertension, that are not harmful to the person taking them if taken in moderate amounts? By moderate, my definition would be not exceeding the minimum daily required allowance.

Dr. RESNICK. Sounds old fashioned, but too little or too much of anything is no good. That is what all the fancy research and equipment turns out to show at the very end. In America, a simple daily multivitamin, just a plain old-fashioned one-a-day multivitamin, not even by brand, provides exact minimum daily requirements.

We are finding out, for example, that deficiencies in certain vitamins can make blood pressure worse. Deficiencies in vitamins B6, peridoxine deficiency, can even cause high blood pressure in people who did not have it. These are new research findings. They are interesting to us. But in terms of everyday practical life, a reasonable and balanced diet provide daily requirements. A one-a-day multivitamin type tablet is not going to be harmful, as far as we know, to almost anyone and will protect people from the kinds of deficiencies that the elderly may be more prone to. If people do have a medical condition on top of that, that is, if they have hypertension or high blood pressure, whatever necessary adjustment needs to be made should be done on a little bit more of an individual basis. The same kind of advice given to everybody might not be helpful to everybody.

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Mr. RINALDO. I think that seems to sum up the feelings of all the panelists, is that correct?

ALL WITNESSES. Yes.

Mr. RINALDO. Except, that if someone reads in tomorrow's paper that a deficiency in B6 can increase blood pressure, they might start taking it.

Dr. FROHLICH. Exactly.

Mr. RINALDO. OK. Once again I want to thank all of you very much. The committee and I will keep in touch with all of you. We recognize the limits on your time but believe me, I think you have rendered a very valuable public service this morning. We are very grateful for your coming here. Thank you again.

[Whereupon, at 12 noon, the committee was adjourned.]

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APPENDIX

PREPARED STATEMENT OF ELIZABETH B. CONGDON, COORDINATOR, CARIDIO-VASCULAR DISEASE AND DIABETES, NEW JERSEY STATE DEPARTMENT OF HEALTH

Hypertension remains a highly prevalent condition with almost 1 adult in 3 affected.

- 29.8% of the 18-74 age population has hypertension
- the rate of hypertension in blacks is 38.2%
- compared to the rate of 28.8% in whites
- the highest rate is 82.9% in black females ages 65-74
- 33% of men have hypertension as compared to 26.8% of women

Hypertension is the highest prevalent condition in persons ages 55 and older in every age, race, sex group with a rate of 50% or greater. After arthritis, hypertension is the most frequently reported chronic condition among the elderly.

Of New Jersey's 7.6 million population, an estimated 2 million people age 18 and over have hypertension

- 9.2% in 18-24 age group
- 13.7% in 25-34 age group
- 23.7% in 35-44 age group
- 41.3% in 45-54 age group
- 52.6% in 55-64 age group
- 64.3% in 65-74 age group

Arthritis, rheumatism and heart conditions are the most common causes of activity restrictions for those 65 and over. Nearly 50% of the elderly who limit their activities do so because of these types of illnesses. Hypertension, visual impairment and diabetes are also major causes of disability.

Hypertensives are at increased risk of death and disability from hypertension-related heart attacks, stroke and kidney disease. This asymptomatic disease (often referred to as the "silent killer") is easily detectable via a blood pressure measurement and treatment has been shown to both lower blood pressure and reduce the risk of these morbid events.

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The economic impact of hypertension is staggering. Diseases of the heart were the most common reasons nationally in 1981 for hospitalization of elderly people. Annual expenditures in the nation for cardiovascular disease have been estimated at $80 billion. Prorated on the basis of total population from the 1980 census, total cost to New Jersey residents from cardiovascular disease would be $2.6 billion annually. The United States Health Care Financing Administration's estimate of national expenditures for personal health care for 1980 indicates an expenditure of $33.2 billion for diseases of the circulatory system. Of this total of $33.2 billion, $14.6 billion has been imputed to heart disease and another $5.1 billion to stroke.

New Jersey's death rates for ischemic heart disease and cerebrovascular disease for the years, 1970, 1975 and 1980 parallel those of the United States. In 1980 New Jersey death rates for ischemic heart disease declined 23.6 percent from 1970 while U.S. rates declined 36.5 percent. New Jersey cerebrovascular rates have declined 33.7 percent while U.S. rates declined 42.8 percent in the same time period.

Although cardiovascular disease mortality has declined since 1950, over one-third of the total reduction has occurred since the establishment of the National High Blood Pressure Education Program and the concurrent widespread growth of community-based hypertension control programs. Deaths from hypertension related disease have continued to decline at a much sharper rate than those categories of cardiovascular diseases not related to hypertension.

Now that initial efforts to reduce morbidity and mortality rates in cardiovascular disease has been successfully implemented, the challenge of continuing that decline remains, and steps need to be taken to catalyze further progress.

The New Jersey State Department of Health Hypertension Control Program is in its tenth year of funding and remains committed to insuring a continued decline in cardiovascular morbidity and mortality rates on behalf of its citizenry through the continuation of its statewide coordinated hypertension control program.

What has been done during the past 10 years? Hypertension services are mandated "core" activities for Local Health Departments in New Jersey. The State Program developed guidelines for Local Health Departments which are implemented at the local level so that quality services are provided consistently throughout the state.

Utilizing federal and state funds, contracts are awarded to local agencies such as health departments, hospitals, neighborhood health centers, home health agencies, so that they will provide hypertension services which include outreach, community organization, screening, one-to-one cardiovascular and diabetes risk factor assessment, referral, follow-up and public, patient and provider education.

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Between 4 and 18 agencies have been funded each year. Reaching the unserved, hard-to-reach population has been emphasized. Unique to this program is that services are brought to the consumer at the worksite and in the community as well as being available in more tradition health care settings. Mass media endeavors have made us all more aware of the need to have our blood pressure checked, and to see a physician if the blood pressure is elevated. Initiating and then continuing treatment is essential.

What has been accomplished? From 1976-1985, a total of 948,641 persons were screened by community-based projects. This includes service to 157,000 people over age 65. Of this total group, 12.2 percent (115,401) had elevated blood pressure readings and were referred for medical evaluation. From 1978 to 1985, 16,368 persons with definite hypertension were newly diagnosed.

We need to continue these education and screening services to the high risk population. Crucial is the continued funding now available through the Preventive Health and Health Services Block Grant.

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Calcium and Hypertension: The Emerging Connection

SINCE RINGER first showed the importance of calcium in cardiac muscle contraction, a role for calcium has been increasingly recognized in mediating various cellular responses to external stimuli involved in neuromuscular function, stimulus-secretion coupling, and humoral target-organ effects. The use of calcium channel-blocking agents in the treatment of hypertension shows the critical importance of calcium in the biochemical control of vascular smooth muscle tone, and thus of blood pressure homeostasis.

Despite these advances, the relation of clinical aspects of calcium metabolism such as dietary calcium intake, renal disposition of calcium, and circulating levels of calcium-regulating hormones, as well as of calcium itself, to disorders of blood pressure regulation such as hypertension remains an ambiguous one. A rapidly expanding literature suggests that alterations of these clinical metabolic variables are indeed found in human hypertensive disease, and that they may contribute to the pathophysiology of hypertension. However, these alterations seem to suggest that calcium may either exacerbate or alleviate hypertension.

The report by McCarron and Morris in this issue (1) and other recent and preliminary reports (2, 3) that show the ability of oral calcium supplements to lower blood pressure in some subjects with essential hypertension not only emphasize the link between hypertensive disease and clinical aspects of calcium metabolism but also suggest the possibility of increased calcium intake as a primary treatment for hypertension. The implications of this line of investigation make it both reasonable and timely to formulate a perspective from which to assess the potential benefit of calcium in hypertension.

What clinical information is available linking calcium and hypertension? Reports in the literature suggest that both calcium excess as well as calcium deficiency may contribute to hypertension. Thus, population surveys show a positive relation between blood pressure and serum calcium levels (4), and increased intracellular free cytosolic calcium levels have been reported in hypertensive persons (5). Furthermore, acute elevation or suppression of circulating calcium levels result in concomitant elevation or suppression of blood pressure (6, 7), and the chronic hypercalcemia of hyperparathyroidism and vitamin D intoxication is also associated with an increased incidence of chronic hypertension (8). These studies all tend to portray calcium as a pathogenetic or exacerbating factor in hypertensive disease.

On the other hand, an inverse relation between dietary calcium intake and blood pressure has been observed (9). At the same time, more calcium may be excreted for a given salt intake (10), and lower serum ionized calcium levels have been measured in hypertensives (11). Lastly, dietary calcium supplementation in normotensive young adults (12), elderly osteoporotic hypertensive persons (2), and those with essential hypertension (1, 3) can result in significantly decreased blood pressure. These data suggest that a relative or absolute calcium deficiency is present

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in hypertension.

Although recent reviews have attempted to rationalize these data and have favored one alternative or the other (13, 14), this may not be the best approach. It may be more productive to note the heterogeneity of human hypertension. This heterogeneity can be assessed biochemically by measurements of known blood pressure regulators such as plasma renin activity. Clinically, the findings that some but not all hypertensive persons are "salt-sensitive" and that hypertensives have a wide spectrum of blood pressure sensitivities to antihypertensive drug therapy suggest that a single pathogenetic mechanism is not the cause of most human hypertension.

It therefore seems reasonable to expect a similar heterogeneity of altered calcium metabolism among human hypertensive populations. This is indeed the case. Different hypertensive subjects, whether categorized according to plasma renin activity (15), dietary salt sensitivity (16), or antihypertensive drug responsiveness (17), show different patterns of calcium metabolism, suggesting a calcium deficiency in some, and calcium excess in others, despite average calcium values still within the normal range. For a given dietary salt intake, hypertensive persons with low renin levels have a calcium metabolic profile of calcium "deficiency," with lower average levels of serum ionized calcium and higher levels of parathyroid hormone and calcitriol when compared with either normotensive persons or other renin subgroups of hypertensive persons (18). Similar findings are observed in primary aldosteronism, a secondary form of low-renin hypertension (19). Furthermore, a high salt intake in salt-sensitive hypertensives induces a fall in serum ionized calcium and a reciprocal elevation in calcitriol levels, each in proportion to the ability of salt to increase the blood pressure (16). Similarly, hypertensive persons most sensitive to the hypotensive effects of nifedipine have the same low renin, lower ionized calcium profile; long-term therapy reverses these initial deviations (17). Hypertensive persons who have a high-renin profile or who are found to be salt insensitive, or whose blood pressure is less responsive to calcium channel blockade tend to have the opposite calcium metabolic pattern, suggesting calcium "excess." Thus, apparently contradictory alternatives may be relevant in different hypertensive populations.

Because calcium metabolism differs in the various biochemical and clinical hypertensive subgroups, hypertensive persons with opposite patterns of calcium metabolism may not respond equally to calcium supplementation. It is important to note McCarron and Morris observed that calcium supplements lowered pressure in some hypertensive subjects, and raised it in others, while pressure remained unchanged in many. The question thus arises, is there any way of determining those patients for whom calcium would be most beneficial? Early evidence suggests higher dietary salt intake, lower plasma renin activity, and lower serum ionized calcium levels may help identify persons with the greatest hypotensive response to oral calcium supplementation, that is, those with indices suggesting a calcium "deficiency." Persons with higher initial levels of serum ionized calcium, higher plasma renin activity at a given salt intake, and lower salt intakes—that is, those with a pattern of calcium "excess"—may have a pressor response to calcium supplements (17).

Conclusions appropriate for the present state-of-the-art are few, but are nonetheless important. First, clinical aspects of calcium metabolism appear linked with the pathophysiology of hypertension, and further investigation to better define this linkage will contribute to an improved understanding of the hypertensive process, and should be encouraged. Second, measurements of serum ionized calcium, calcium regulating hormones, or other calcium metabolic indices may be diagnostically useful in targeting differing pathogenetic and therapeutic subgroups of hypertension. This approach may allow a more individual approach to the hypertensive patient than has been possible. Third, oral calcium supplements can significantly alter blood pressure in normotensive and hypertensive persons, and may become a valuable nonpharmacologic option in the treatment of hypertension.

No specific dietary or other recommendations with regard to calcium should be made at this time for the hypertensive population as a whole. Our efforts at present should be to confirm the long-term antihypertensive efficacy of calcium supplements over the many months or years one may expect them to be used, and to assess the potential risks. We must also strive to define those criteria by which the benefit to a given hypertensive or subgroup of hypertensive persons can be predicted. Indeed, after many decades, the antihypertensive efficacy of moderate or severe dietary salt restriction is still debated, in part because of a failure to focus on those patients most likely to benefit (20). Lastly, we must integrate our understanding and use of calcium within a more general framework including other mineral, humoral, and neural elements. Controversies regarding whether one mineral is more important than another in the pathogenesis or therapy of hypertension should be discouraged. The challenges now before us remain in research, but the promises are ones of great potential benefit to the millions with hypertension. (LAWRENCE M. RESNICK, M.D.; *The New York Hospital-Cornell University Medical Center; New York, New York*)

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Devices Used for Self-Measurement of Blood Pressure

Revised Statement of the National High Blood Pressure Education Program

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Several factors have necessitated an update of the 1980 report of the National High Blood Pressure Education Program on blood pressure measurement devices used by consumers.[1] First, new information relating to the use and accuracy of blood pressure measurement devices has become available.[2] Second, due to heightened awareness and improved technology, sales and use of self-measurement equipment (including home blood pressure devices and automated machines) have increased.[3] Last, and of equal importance, is the increasing interest in ambulatory blood pressure monitoring systems among health professionals, leading to questions concerning the appropriateness of their use in the control of high blood pressure.[4,5]

The statement that follows addresses the use and accuracy of three types of blood pressure measurement equipment: portable home devices, stationary automated machines, and noninvasive ambulatory monitors. Benefits and concerns relating to each type of equipment are discussed. Recommendations regarding the use of devices for self-measurement are then presented. Specific information about techniques for blood pressure measurement is available from local chapters of the American Red Cross, state and local high blood pressure control programs, and health care professionals. (An annotated bibliography on blood pressure measurement, which includes information on blood pressure measurement instruction booklets, is available from the High Blood Pressure Information Center, 120/80 National Institutes of Health, Bethesda, MD 20892.)

This statement contains information for the general public, the patient with hypertension, and the health professional. Our purpose in revising the 1980 statement about blood pressure measuring equipment and its uses is to help put this new information about self-measurement into perspective.

ACCURACY AND MAINTENANCE OF AVAILABLE EQUIPMENT

Home Blood Pressure Measuring Devices

Several million families have already purchased home blood pressure measurement devices. Such devices may consist of a mercury sphygmomanometer, an aneroid manometer, or an electronic device.

The mercury sphygmomanometer is calibrated when manufactured, and recalibration is unnecessary as long as the meniscus of the mercury column is exactly at 0 when the cuff is deflated. If the mercury column is not at 0 or the mercury column is dirty, the instrument should be returned to the manufacturer for cleaning and recalibration. The mercury sphygmomanometer is considered the most accurate and reliable device when properly used.

Most home blood pressure kits include a blood pressure cuff, an aneroid manometer, and a stethoscope; and they should be reliable, accurate, and relatively inexpensive. According to the American Heart Association and American Red Cross, they should be calibrated at least once a year against a standard mercury sphygmomanometer using a Y-connector to assure consistent accuracy.[6]

Nonelectronic mercury and aneroid home blood pressure measurement devices used in conjunction with a standard stethoscope are reasonably accurate. The mercury sphygmomanometer, when used properly, is still the standard against which all other blood pressure measurement devices are compared.

The new digital readout (electronic) devices are easiest of the three to use and do not require the use of a stethoscope, but they are more complex instruments. Many of these units are fully automated; the push of a button inflates and deflates the cuff. While more expensive, these automated devices may be advantageous for those concerned about their ability to measure pressure accurately. However, because of their greater complexity and sensitivity, they are more likely to become inaccurate and should be recalibrated more frequently than once a year. One note of caution: these devices are highly sensitive. If the cuff is improperly placed or if arm motion occurs during measurement, errors will occur. Patients should be advised to repeat the reading if unusual blood pressures are noted.

Digital readout (electronic) home blood pressure measuring devices are being improved. At present, they are sufficiently accurate for home use in most instances if patients and the health care professionals responsible are aware of the potential problems.

Stationary Automated Machines

The stationary automated machine, whether coin operated or to be used free of charge, may be found in work sites, pharmacies, banks, airports, and other public places. Evaluation of commonly used stationary blood pressure devices indicates that blood pressure readings can vary considerably between machines. The date of the last calibration of the device is the only measure of reliability, and often information about the last calibration date is not provided to users. Machine-recorded blood pressures may vary by 5 to 10 mm Hg or more (for both systolic and diastolic pressures) when compared with blood pressures taken by trained observers or by the random zero blood pressure method. The majority of errors are on the high side.[4]

Automated machines, then, are of greater value when calibrated regularly. Users should be advised that the reliability of automated or semiautomated stationary devices is limited and urged to seek medical counsel prior to taking any action as a result of a blood pressure reading on one of these machines.

Noninvasive Ambulatory Blood Pressure Monitors

While home blood pressure measuring devices and stationary machines are now readily accessible and used at the discretion of the public, ambulatory blood pressure monitoring systems are prescribed and used solely under physician supervision. These portable devices for measurement of blood pressure have been available for a number of years, but have only recently come into greater use. Noninvasive ambulatory blood pressure monitoring systems can be defined as devices that allow systolic and diastolic blood pressure and heart rate to be measured and recorded repeatedly during a protracted time period in subjects as they continue their routine activities.[5]

A *few fully automatic* portable devices measure the blood pressure and record it automatically, while *semiautomatic* portable devices require the patient to inflate the cuff. These devices are battery powered, thereby permitting the recording of blood pressures in outpatients who are ambulatory or sleeping. Available noninvasive systems are equipped with standard-sized blood pressure cuffs. Effective use of most models does require active patient participation, and prospective patient education is therefore essential.

It is important to note that continuous 24-hour monitoring systems are for use in a selected number of patients and are not intended as a routine, practical, or cost-effective means for following up the majority of patients being treated for essential hypertension. Determination of the full clinical usefulness of ambulatory blood pressure monitoring requires further investigation. Limitations include the following:

1. The semiautomated devices are reasonably reliable but do not provide data while patients are sleeping or at other times when patients cannot manually inflate the cuff.

2. Reliability of the fully automated devices varies, even in experienced hands. Approximately 20% of the time, technical problems can result in inaccurate readings (Jan I. M. Drayer, MD, 1984, unpublished paper available from the High Blood Pressure Information Center).

3. With both automated and semiautomated devices, motion during blood pressure measurement causes false readings.

BENEFITS AND CONCERNS ABOUT SELF-ADMINISTERED BLOOD PRESSURE MEASUREMENT

The following considerations about the three types of self-administered blood pressure measurement devices are applicable in all settings, including work sites, physicians' and other health professionals' offices, and patients' homes.

Uses of home blood pressure measuring devices include

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the measurement of blood pressure by persons who are not receiving treatment and by patients monitoring the progress of their medically supervised treatment. Many people—from the general public to patients with hypertension—are also using the stationary machines. Thus, both types of devices are being used for monitoring in individuals with normal as well as high blood pressure. Ambulatory devices, however, should be used exclusively under the direction of a qualified physician.

Benefits

Whether used by consumers from among the general public or by patients with hypertension, instruments for self-measurement of blood pressure should be accompanied by scientifically accurate and complete educational material concerning use of the equipment and interpretation of results.

For the General Public

1. Self-administered measurement may be useful in detecting an elevated blood pressure in persons previously unaware of the problem.

2. For individuals with borderline pressures, the data collected may be helpful in documenting blood pressure patterns, which may assist in determining the proper treatment program.

For Patients With the Diagnosis of Hypertension

1. Blood pressure measurement at home, at the work site, or elsewhere allows patients and their families to participate actively in the treatment program.

2. For some patients receiving antihypertensive therapy, visual evidence of blood pressure change provided by readily available readings may enhance compliance with the prescribed treatment program.

3. Measurements obtained outside the physician's office may aid him or her in making treatment decisions for patients with hypertension and in evaluating efficacy of therapy, adjusting therapy, or both. Self-measurement of blood pressure may be particularly useful for patients on a prescribed treatment program that includes nonpharmacological measures, with or without antihypertensive pharmacological agents.

4. Self-measurement may lead to simplification of the treatment program, which may result in reduction of medication dosages, fewer side effects, and increased compliance.

5. Self-measurement may obviate the need for more frequent office visits during initial therapy when the treatment program is being adjusted. Moreover, these data may be used by the physician to lengthen the intervals between visits once the "goal" blood pressure is achieved and maintained. (The initial goal of antihypertensive therapy is to achieve and maintain diastolic pressures lower than 90 mm Hg, if feasible. A reasonable further goal is the lowest diastolic pressure consistent with safety and tolerance.[6])

CONCERNS

On balance, concerns about self-administered blood pressure measurement must be considered along with the benefits. Such concerns include the possibility of inadequate training in measurement technique, consequent inaccurate readings, and misunderstanding of the observed measurements.

For the General Public

1. One elevated blood pressure reading, or even several, is not an adequate basis for a diagnosis of hypertension. Elevated readings obtained through self-measurement are only an indication that further evaluation is needed. The diagnosis of hypertension can only be made by a physician who interprets the significance of self-obtained blood pressure readings along with other data relevant to the individual patient.

2. Repeated high blood pressure readings resulting from machine artifact could lead an individual to a false self-diagnosis of "high blood pressure." Users should be made aware of the possibility and implications of such inaccurate readings. Similarly, artifactually low measurements also occur in a small percentage of persons.

For Patients With the Diagnosis of Hypertension

1. Home blood pressure measurement may be more suitable for some patients than for others. Some patients may become overly conscious of their blood pressure and alarmed at the normal fluctuations in pressure associated with daily living. Misinterpretation or overreaction to one or more measurements may cause psychological distress and even inappropriate self-adjustment of drug therapy. Such adjustment, without proper medical consultation, may lead to treatment errors, medication side effects, or other problems.

2. Inadequate instruction on how to use a blood pressure measurement device may lead to inaccurate readings. A careful, prospective education program on the use of the device and the meaning of the results is necessary before these instruments are recommended and used.

3. Purchase of equipment with a standard-sized adult cuff may result in false readings if the cuff is too large or too small for the subject's arm. Recommendations on the proper cuff size for a given arm girth are available.[6]

4. A hectic or noisy environment during measurement may result in an excessively high reading.

RECOMMENDATIONS FOR SELF-MEASUREMENT DEVICES

With proper safeguards, it is possible for consumers, including the general public and patients with identified hypertension, to benefit from self-measurement of blood pressure. Misinterpretation and misuse could be minimized if certain actions are taken. The National High Blood Pressure Education Program Coordinating Committee recommends the following:

Use

1. Users of any home or stationary device should be provided with information about where to follow up an elevated reading and should be advised that counsel about their blood pressure may be obtained from physicians, other health professionals, voluntary health agencies, employee health programs, and public health departments.

2. Regardless of the type of equipment or where it is being used, consumers need complete written instructions on how to measure blood pressure. For example, printed instructions should always specify that the arm be supported and bared and that the appropriate size cuff be used. Such information is available from local chapters of the American Red Cross, the National Kidney Foundation (2 Park Ave, New York, NY 10016), and the High Blood Pressure Information Center.

3. The health care professional who recommends home measurement should provide or arrange for patient instruction in measurement, initial and periodic calibration, and record-keeping techniques.

4. The health care professional considering home blood pressure measurement for a patient or the consumer considering purchase of a home device should remember that impaired hearing or vision, reduced mental acuity, or poor physical coordination may cause special difficulties in using the equipment.

5. In addition to assuring that each patient understands the procedure, the supervising professional should make a particular effort to recommend accurate and reliable equipment.

Measures to Maximize Benefits

1. The Food and Drug Administration, under the authority of PL 94-295 of the *Medical Devices Amendment of 1976*, should adopt manufacturing and performance standards and labeling requirements for use and maintenance of blood pressure measurement devices.

2. Manufacturers should include printed instructions about calibration of these devices with every instrument sold. All devices installed in public places should be calibrated at appropriate intervals, and a record attesting to this calibration should be prominently displayed on the devices.

3. Manufacturers and distributors should include clear printed instructions and supplementary information about the use of the device and about blood pressure to all persons purchasing self-measurement devices, including specifics about (*a*) the nature of high blood pressure, (*b*) the significance of elevated readings, (*c*) the necessity of seeking a source of care, and (*d*) the way to obtain additional counsel and assistance.

4. Printed information should be available wherever automated machines are used. Such material should also be provided in the packaging of all home devices to all purchasers at the point of purchase. Such materials for users should include (*a*) information on the nature of blood pressure and its variability from minute to minute and in different body positions, (*b*) the asymptomatic nature of hypertension, (*c*) the difference between an elevated blood pressure reading and the diagnosis of hypertension, (*d*) the inadequacy of self-administered blood pressure measurement as a substitute for periodic observation and evaluation by a physician or other health professional, and (*e*) information on the significance of an elevated blood pressure reading and the subsequent course of action to be taken.

Referral

Educational material on blood pressure levels and referral thresholds should conform to the most recent *Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure*,[6] available from the High Blood Pressure Information Center. The 1984 report states the following:

1. Blood pressure of less than 140/90 mm Hg is considered a normal reading in adults, although a diastolic pressure (the second or lower number) of 85 to 89 mm Hg warrants further observation.

2. A single elevated reading does not constitute a diagnosis of hypertension but is only a sign that further observation is required.

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3. **Blood pressure equal to or greater than 140/90 mm Hg is considered elevated. If on initial measurement the** diastolic pressure is 105 to 114 mm Hg, one should evaluate or promptly refer the patient to a source of care within two weeks. If it is 115 mm Hg or higher, the evaluation or referral should be done *immediately*.

4. Persons known to have hypertension should continue with their prescribed treatment programs and report their blood pressures to their clinicians at regularly scheduled visits.

The Working Group to Update the 1980 National High Blood Pressure Education Program Statement on Blood Pressure Measurement Devices Used by Consumers includes Dr Hunt, Chairman, Center for Health Sciences, University of Tennessee, Memphis; Dr Frohlich, Alton Ochsner Medical Foundation, New Orleans; Dr Mosert, Yale University School of Medicine, New Haven, Conn; Dr Roccella, National High Blood Pressure Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Md; and Ms Keighley, Kappa Systems Inc, Washington, DC.

The Working Group wishes to acknowledge the following individuals who contributed to the development of this article: Jan I. M. Drayer, MD; Frances W. Gillen; Walter M. Kirkendall, MD; Sandra Maksche; Sheldon G. Sheps, MD; and Michael A. Weber, MD.

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Member Organizations of the National High Blood Pressure Education Program Coordinating Committee

Ad Hoc Committee on Cardiovascular/Pulmonary Disease Risk Factors in Minority Populations
American Academy of Family Physicians
American Academy of Ophthalmology
American Academy of Physician Assistants
American Association of Occupational Health Nurses
American College of Cardiology
American College of Chest Physicians
American College of Physicians
American College of Preventive Medicine
American Dental Association
American Dietetic Association
American Heart Association
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The silent killer is hypertension or nign blood pressure.

Hign blood pressure is one of the nation's major public health problems. It is a lifelong disease that cannot be cured. But it CAN be controlled.

First, you have to understand a little more about the condition and what constitutes hypertension.

Blood pressure is represented hy two numbers expressed in a fraction. The top number refers to the pumping, or systolic pressure of the blood; the lower number represents the diastolic, or resting pressure.

The Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure defines hypertension as follows: A diastolic blood pressure of less than 85 mm Hg is considered normal; 85 to 89 mm Hg is nigh normal and bears watching; 90 to 104 mm Hg on repeated visits is mild high blood pressure; 105 to 114 mm Hg is moderate high; and a reading of 115 or higher is severe.

The committee classifies a reading of 140 to 159 mm Hg as borderline isolated systolic hypertension (when the diastolic pressure is less than 90) and a systolic pressure at or above 160 mm Hg as isolated systolic hypertension (when the diastolic pressure is less tnan 90).

What do all these readings mean in terms of your health?

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Even mild nigh blood pressure is dangerous if untreated because it can lead silently but directly to crippling or deadly consequences—heart attack, stroke, and kidney failure. High blood pressure is especially dangerous because it has no outward signs. A person can have it and not even know.

High blood pressure rarely causes dizziness, nervousness or headaches. As a result, many people live with high blood pressure for years without knowing it, but they still suffer the physical effects.

It is very important for people to have a regular blood pressure check-up and, if it is nigh, to follow the prescribed treatment for life. Along with drugs, salt reduction, weight loss for the overweight, and exercise are among the most important ways to treat high blood pressure.

Doctors have also found that there is a chance of more than one member of a family having hypertension. Family members will benefit if they learn early on how to deal with nigh blood pressure.

Above all, make control your lifetime goal for your blood pressure. If you are under treatment for hypertension, take your medications as prescribed, lose those extra pounds, use salt sensibly, exercise regularly, and if you smoke, stop.

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